(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) **EP 3 069 747 B1**

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
13.07.2022 Bulletin 2022/28

(21) Application number: **15159272.2**

(22) Date of filing: **16.03.2015**

(51) International Patent Classification (IPC):
A61M 16/06 *(2006.01)*

(52) Cooperative Patent Classification (CPC):
A61M 16/06; A61M 2016/0661

(54) PATIENT INTERFACE, SEAL FORMING STRUCTURE AND METHOD OF MANUFACTURING OF THE SAME

PATIENTENSCHNITTSTELLE, DICHTUNGSBILDENDE STRUKTUR UND VERFAHREN ZUR HERSTELLUNG DAVON

INTERFACE PATIENT, STRUCTURE DE FORMATION DE JOINT ET PROCÉDÉ DE FABRICATION ASSOCIÉ

(84) Designated Contracting States:
AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO RS SE SI SK SM TR

(43) Date of publication of application:
21.09.2016 Bulletin 2016/38

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Description

1 BACKGROUND OF THE TECHNOLOGY

1.1 FIELD OF THE TECHNOLOGY

[0001] The present technology relates to one or more of the detection, diagnosis, treatment, prevention and amelioration of respiratory-related disorders. The present technology also relates to medical devices or apparatus, and their use. In particular, the present technology is directed to a patient interface and a seal forming structure for such a patient interface, as well as manufacturing methods of the same.

1.2 DESCRIPTION OF THE RELATED ART

1.2.1 Human Respiratory System and its Disorders

[0002] The respiratory system of the body facilitates gas exchange. The nose and mouth form the entrance to the airways of a patient.

[0003] The airways include a series of branching tubes, which become narrower, shorter and more numerous as they penetrate deeper into the lung. The prime function of the lung is gas exchange, allowing oxygen to move from the air into the venous blood and carbon dioxide to move out. The trachea divides into right and left main bronchi, which further divide eventually into terminal bronchioles. The bronchi make up the conducting airways, and do not take part in gas exchange. Further divisions of the airways lead to the respiratory bronchioles, and eventually to the alveoli. The alveolated region of the lung is where the gas exchange takes place, and is referred to as the respiratory zone. See "Respiratory Physiology", by John B. West, Lippincott Williams & Wilkins, 9th edition published 2011.

[0004] A range of respiratory disorders exist. Certain disorders may be characterised by particular events, e.g. apneas, hypopneas, and hyperpneas.

[0005] Obstructive Sleep Apnea (OSA), a form of Sleep Disordered Breathing (SDB), is characterized by events including occlusion or obstruction of the upper air passage during sleep. It results from a combination of an abnormally small upper airway and the normal loss of muscle tone in the region of the tongue, soft palate and posterior oropharyngeal wall during sleep. The condition causes the affected patient to stop breathing for periods typically of 30 to 120 seconds in duration, sometimes 200 to 300 times per night. It often causes excessive daytime somnolence, and it may cause cardiovascular disease and brain damage. The syndrome is a common disorder, particularly in middle aged overweight males, although a person affected may have no awareness of the problem. *See* US Patent No. 4,944,310 (Sullivan).

[0006] Cheyne-Stokes Respiration (CSR) is another form of sleep disordered breathing. CSR is a disorder of a patient's respiratory controller in which there are rhythmic alternating periods of waxing and waning ventilation known as CSR cycles. CSR is characterised by repetitive de-oxygenation and re-oxygenation of the arterial blood. It is possible that CSR is harmful because of the repetitive hypoxia. In some patients CSR is associated with repetitive arousal from sleep, which causes severe sleep disruption, increased sympathetic activity, and increased afterload. *See* US Patent No. 6,532,959 (Berthon-Jones).

[0007] Obesity Hyperventilation Syndrome (OHS) is defined as the combination of severe obesity and awake chronic hypercapnia, in the absence of other known causes for hypoventilation. Symptoms include dyspnea, morning headache and excessive daytime sleepiness.

[0008] Chronic Obstructive Pulmonary Disease (COPD) encompasses any of a group of lower airway diseases that have certain characteristics in common. These include increased resistance to air movement, extended expiratory phase of respiration, and loss of the normal elasticity of the lung. Examples of COPD are emphysema and chronic bronchitis. COPD is caused by chronic tobacco smoking (primary risk factor), occupational exposures, air pollution and genetic factors. Symptoms include: dyspnea on exertion, chronic cough and sputum production.

[0009] Neuromuscular Disease (NMD) is a broad term that encompasses many diseases and ailments that impair the functioning of the muscles either directly via intrinsic muscle pathology, or indirectly via nerve pathology. Some NMD patients are characterised by progressive muscular impairment leading to loss of ambulation, being wheelchair-bound, swallowing difficulties, respiratory muscle weakness and, eventually, death from respiratory failure. Neuromuscular disorders can be divided into rapidly progressive and slowly progressive: (i) Rapidly progressive disorders: Characterised by muscle impairment that worsens over months and results in death within a few years (e.g. Amyotrophic lateral sclerosis (ALS) and Duchenne muscular dystrophy (DMD) in teenagers); (ii) Variable or slowly progressive disorders: Characterised by muscle impairment that worsens over years and only mildly reduces life expectancy (e.g. Limb girdle, Facioscapulohumeral and Myotonic muscular dystrophy). Symptoms of respiratory failure in NMD include: increasing generalised weakness, dysphagia, dyspnea on exertion and at rest, fatigue, sleepiness, morning headache, and difficulties with concentration and mood changes.

[0010] Chest wall disorders are a group of thoracic deformities that result in inefficient coupling between the respiratory muscles and the thoracic cage. The disorders are usually characterised by a restrictive defect and share the potential of long term hypercapnic respiratory failure. Scoliosis and/or kyphoscoliosis may cause severe respiratory failure. Symptoms of respiratory failure include: dyspnea on exertion, peripheral oedema, orthopnea, repeated chest infections, morning headaches, fatigue, poor sleep quality and loss of appetite.

[0011] A range of therapies have been used to treat or ameliorate such conditions. Furthermore, otherwise healthy individuals may take advantage of such therapies to prevent respiratory disorders from arising. However, these have a number of shortcomings.

1.2.2 Therapy

[0012] Continuous Positive Airway Pressure (CPAP) therapy has been used to treat Obstructive Sleep Apnea (OSA). The hypothesis is that continuous positive airway pressure acts as a pneumatic splint and may prevent upper airway occlusion by pushing the soft palate and tongue forward and away from the posterior oropharyngeal wall. Treatment of OSA by CPAP therapy may be voluntary, and hence patients may elect not to comply with therapy if they find devices used to provide such therapy one or more of: uncomfortable, difficult to use, expensive and aesthetically unappealing.

[0013] Non-invasive ventilation (NIV) provides ventilatory support to a patient through the upper airways to assist the patient in taking a full breath and/or maintain adequate oxygen levels in the body by doing some or all of the work of breathing. The ventilatory support is provided via a patient interface. NIV has been used to treat CSR, OHS, COPD, MD and Chest Wall disorders. In some forms, the comfort and effectiveness of these therapies may be improved.

[0014] Invasive ventilation (IV) provides ventilatory support to patients that are no longer able to effectively breathe themselves and may be provided using a tracheostomy tube. In some forms, the comfort and effectiveness of these therapies may be improved.

1.2.3 Diagnosis and Treatment Systems

[0015] These therapies may be provided by a treatment system or device. Systems and devices may also be used to diagnose a condition without treating it.

[0016] A treatment system may comprise a Respiratory Pressure Therapy Device (RPT device), an air circuit, a humidifier, a patient interface, and data management.

[0017] Another form of treatment system is a mandibular repositioning device.

1.2.3.1 Patient Interface

[0018] A patient interface may be used to interface respiratory equipment to its wearer, for example by providing a flow of air to an entrance to the airways. The flow of air may be provided via a mask to the nose and/or mouth, a tube to the mouth or a tracheostomy tube to the trachea of a patient. Depending upon the therapy to be applied, the patient interface may form a seal, e.g., with a region of the patient's face, to facilitate the delivery of gas at a pressure at sufficient variance with ambient pressure to effect therapy, e.g., at a positive pressure of about 10 cmH_2O relative to ambient pressure. For other forms of therapy, such as the delivery of oxygen, the patient interface may not include a seal sufficient to facilitate delivery to the airways of a supply of gas at a positive pressure of about 10 cmH_2O.

[0019] The design of a patient interface presents a number of challenges. The face has a complex three-dimensional shape. The size and shape of noses varies considerably between individuals. Since the head includes bone, cartilage and soft tissue, different regions of the face respond differently to mechanical forces. The jaw or mandible may move relative to other bones of the skull. The whole head may move during the course of a period of respiratory therapy.

[0020] As a consequence of these challenges, some masks suffer from being one or more of obtrusive, aesthetically undesirable, costly, poorly fitting, difficult to use, and uncomfortable especially when worn for long periods of time or when a patient is unfamiliar with a system. For example, masks designed solely for aviators, masks designed as part of personal protection equipment (e.g. filter masks), SCUBA masks, or for the administration of anaesthetics may be tolerable for their original application, but nevertheless such masks may be undesirably uncomfortable to be worn for extended periods of time, e.g., several hours. This discomfort may lead to a reduction in patient compliance with therapy. This is even more so if the mask is to be worn during sleep.

[0021] CPAP therapy is highly effective to treat certain respiratory disorders, provided patients comply with therapy. If a mask is uncomfortable, or difficult to use a patient may not comply with therapy. Since it is often recommended that a patient regularly wash their mask, if a mask is difficult to clean (e.g., difficult to assemble or disassemble), patients may not clean their mask and this may impact on patient compliance.

[0022] While a mask for other applications (e.g. aviators) may not be suitable for use in treating sleep disordered breathing, a mask designed for use in treating sleep disordered breathing may be suitable for other applications.

[0023] For these reasons, patient interfaces for delivery of CPAP during sleep form a distinct field.

1.2.3.1.1 Seal-forming portion

[0024] Patient interfaces may include a seal-forming portion. Since it is in direct contact with the patient's face, the shape and configuration of the seal-forming portion can have a direct impact the effectiveness and comfort of the patient interface.

[0025] A patient interface may be partly characterised according to the design intent of where the seal-forming portion is to engage with the face in use. In one form of patient interface, a seal-forming portion may comprise two sub-portions to engage with respective left and right nares. In one form of patient interface, a seal-forming portion may comprise a single element that surrounds both nares in use. Such single element may be designed to for example overlay an upper lip region and a nasal bridge region of a face. In one form of patient interface a seal-forming portion may comprise an element that surrounds a mouth region in use, e.g. by forming a seal on a lower lip region of a face. In one form of patient interface, a seal-forming portion may comprise a single element that surrounds both nares and a mouth region in use. These different types of patient interfaces may be known by a variety of names by their manufacturer including nasal masks, full-face masks, nasal pillows, nasal puffs and oro-nasal masks.

[0026] A seal-forming portion that may be effective in one region of a patient's face may be inappropriate in another region, e.g. because of the different shape, structure, variability and sensitivity regions of the patient's face. For example, a seal on swimming goggles that overlays a patient's forehead may not be appropriate to use on a patient's nose.

[0027] Certain seal-forming portions may be designed for mass manufacture such that one design fit and be comfortable and effective for a wide range of different face shapes and sizes. To the extent to which there is a mismatch between the shape of the patient's face, and the seal-forming portion of the mass-manufactured patient interface, one or both must adapt in order for a seal to form.

[0028] One type of seal-forming portion extends around the periphery of the patient interface, and is intended to seal against the patient's face when force is applied to the patient interface with the seal-forming portion in confronting engagement with the patient's face. The seal-forming portion may include an air or fluid filled cushion, or a moulded or formed surface of a resilient seal element made of an elastomer such as a rubber. With this type of seal-forming portion, if the fit is not adequate, there will be gaps between the seal-forming portion and the face, and additional force will be required to force the patient interface against the face in order to achieve a seal.

[0029] Another type of seal-forming portion incorporates a flap seal of thin material positioned about the periphery of the mask so as to provide a self-sealing action against the face of the patient when positive pressure is applied within the mask. Like the previous style of seal forming portion, if the match between the face and the mask is not good, additional force may be required to achieve a seal, or the mask may leak. Furthermore, if the shape of the seal-forming portion does not match that of the patient, it may crease or buckle in use, giving rise to leaks.

[0030] Another type of seal-forming portion may comprise a friction-fit element, e.g. for insertion into a naris, however some patients find these uncomfortable.

[0031] Another form of seal-forming portion may use adhesive to achieve a seal. Some patients may find it inconvenient to constantly apply and remove an adhesive to their face.

[0032] A range of patient interface seal-forming portion technologies are disclosed in the following patent applications, assigned to ResMed Limited: WO 1998/004,310; WO 2006/074,513; WO 2010/135,785.

[0033] One form of nasal pillow is found in the Adam Circuit manufactured by Puritan Bennett. Another nasal pillow, or nasal puff is the subject of US Patent 4,782,832 (Trimble et al.), assigned to Puritan-Bennett Corporation.

[0034] ResMed Limited has manufactured the following products that incorporate nasal pillows: SWIFT™ nasal pillows mask, SWIFT™ II nasal pillows mask, SWIFT™ LT nasal pillows mask, SWIFT™ FX nasal pillows mask and MIRAGE LIBERTY™ full-face mask. The following patent applications, assigned to ResMed Limited, describe examples of nasal pillows masks: International Patent Application WO2004/073,778 (describing amongst other things aspects of the ResMed Limited SWIFT™ nasal pillows), US Patent Application 2009/0044808 (describing amongst other things aspects of the ResMed Limited SWIFT™ LT nasal pillows); International Patent Applications WO 2005/063,328 and WO 2006/130,903 (describing amongst other things aspects of the ResMed Limited MIRAGE LIBERTY™ full-face mask); International Patent Application WO 2009/052,560 (describing amongst other things aspects of the ResMed Limited SWIFT™ FX nasal pillows).

1.2.3.1.2 Positioning and stabilising

[0035] A seal-forming portion of a patient interface used for positive air pressure therapy is subject to the corresponding force of the air pressure to disrupt a seal. Thus a variety of techniques have been used to position the seal-forming portion, and to maintain it in sealing relation with the appropriate portion of the face.

[0036] One technique is the use of adhesives. See for example US Patent Application Publication No. US

2010/0000534. However, the use of adhesives may be uncomfortable for some.

[0037] Another technique is the use of one or more straps and/or stabilising harnesses. Many such harnesses suffer from being one or more of ill-fitting, bulky, uncomfortable and awkward to use.

1.2.3.1.3 Vent technologies

[0038] Some forms of patient interface systems may include a vent to allow the washout of exhaled carbon dioxide. The vent may allow a flow of gas from an interior space of the patient interface, e.g., the plenum chamber, to an exterior of the patient interface, e.g., to ambient. The vent may comprise an orifice and gas may flow through the orifice in use of the mask. Many such vents are noisy. Others may become blocked in use and thus provide insufficient washout. Some vents may be disruptive of the sleep of a bed-partner 1100 of the patient 1000, e.g. through noise or focussed airflow.

[0039] ResMed Limited has developed a number of improved mask vent technologies. *See* International Patent Application Publication No. WO 1998/034,665; International Patent Application Publication No. WO 2000/078,381; US Patent No. 6.581.594; US Patent Application Publication No. US 2009/0050156; US Patent Application Publication No. 2009/0044808.

[0040] Table of noise of prior masks (ISO 17510-2:2007, 10 cmH_2O pressure at 1m)

Mask name	Mask type	A-weighted sound power level dB (A) (uncertainty)	A-weighted sound pressure dB (A) (uncertainty)	Year (approx.)
Glue-on (*)	nasal	50.9	42.9	1981
ResCare standard (*)	nasal	31.5	23.5	1993
ResMed Mirage™ (*)	nasal	29.5	21.5	1998
ResMed UltraMirage™	nasal	36 (3)	28 (3)	2000
ResMed Mirage Activa™	nasal	32 (3)	24 (3)	2002
ResMed Mirage Micro™	nasal	30 (3)	22 (3)	2008
ResMed Mirage™ SoftGel	nasal	29 (3)	22 (3)	2008
ResMed Mirage™ FX	nasal	26 (3)	18 (3)	2010
ResMed Mirage Swift™ (*)	nasal pillows	37	29	2004
ResMed Mirage Swift™ II	nasal pillows	28 (3)	20 (3)	2005
ResMed Mirage Swift™ LT	nasal pillows	25 (3)	17 (3)	2008
ResMed AirFit P10	nasal pillows	21 (3)	13 (3)	2014

[0041] (* one specimen only, measured using test method specified in ISO3744 in CPAP mode at 10 cmH_2O)Sound pressure values of a variety of objects are listed below

Object	A-weighted sound pressure dB (A)	Notes
Vacuum cleaner: Nilfisk Walter Broadly Litter Hog: B+ Grade	68	ISO3744 at 1m distance

(continued)

Object	A-weighted sound pressure dB (A)	Notes
Conversational speech	60	1m distance
Average home	50	
Quiet library	40	
Quiet bedroom at night	30	
Background in TV studio	20	

1.2.3.2 Mandibular repositioning

[0042] A mandibular repositioning device (MRD) or mandibular advancement device (MAD) is one of the treatment options for sleep apnea and snoring. It is an adjustable oral appliance available from a dentist or other supplier that holds the lower jaw (mandible) in a forward position during sleep. The MRD is a removable device that a patient inserts into their mouth prior to going to sleep and removes following sleep. Thus, the MRD is not designed to be worn all of the time. The MRD may be custom made or produced in a standard form and includes a bite impression portion designed to allow fitting to a patient's teeth. This mechanical protrusion of the lower jaw expands the space behind the tongue, puts tension on the pharyngeal walls to reduce collapse of the airway and diminishes palate vibration.

[0043] In certain examples a mandibular advancement device may comprise an upper splint that is intended to engage with or fit over teeth on the upper jaw or maxilla and a lower splint that is intended to engage with or fit over teeth on the lower jaw or mandible. The upper and lower splints are connected together laterally via a pair of connecting rods. The pair of connecting rods is fixed symmetrically on the upper splint and on the lower splint.

[0044] In such a design the length of the connecting rods is selected such that when the MRD is placed in a patient's mouth the mandible is held in an advanced position. The length of the connecting rods may be adjusted to change the level of protrusion of the mandible. A dentist may determine a level of protrusion for the mandible that will determine the length of the connecting rods.

[0045] Some MRDs are structured to push the mandible forward relative to the maxilla while other MADs, such as the ResMed Narval CC™ MRD are designed to retain the mandible in a forward position. This device also reduces or minimises dental and temporo-mandibular joint (TMJ) side effects. Thus, it is configured to minimises or prevent any movement of one or more of the teeth.

1.2.3.3 Patient interfaces and seal forming structures of interest for the present technology

[0046] Turning back to the seal forming structures, there are commonly associated the following challenges: At the one hand, a substantially air tight seal should be provided by the seal forming structure. In this regard, it may desirable that the seal forming structure is securely pressed onto the patient's face. On the other hand, patient comfort is also desirable. In this regard, it is not desirable to firmly press the seal forming structure against the patient's face, as this may result in pressure marks, pressure sores and pain of the patient; in particular, as the respective devices are typically worn for several hours, e.g. the complete duration of the night's sleep. Ultimately, this may also result in the patient not being compliant with the therapy. That is. it is generally a desire to provide a seal forming structure, which, at the same time, firmly seals an interior of the patient interface from an exterior of the patient interface and, is also comfortable for the patient to wear.

[0047] WO 2007/104042 A2 relates to a seal that contacts a portion of a patient to provide a comfortable interface between an external device, such as a respiratory mask, and the patient, wherein the seal includes an elastic casing filled with a soft gel substance having a cone penetration of from about 5 to 200 penetrations.

[0048] WO 2009/062265 A1 relates to a cushion assembly for use with a respiratory mask including a bladder filled with the combination of a gel having a first indentation hardness and a gel having a second indentation hardness.

[0049] WO2014125066 describes a medical support comprising a sheet of heat moldable thermoplastic material and a removable device.

2 BRIEF SUMMARY OF THE TECHNOLOGY

[0050] In order to achieve this, it may be desirable to provide a seal forming structure well fitted to the patient. It may thus be a first object of the present technology to provide a seal forming structure, as well as a corresponding patient

interface, overcoming or at least alleviating the problems associated with the prior art. In other words, it may be an object of the present technology to provide a seal forming structure and a respective patient interface having improved characteristics as regards sealing capabilities and patient comfort.

[0051] It is a further object of the present technology to also provide methods of manufacturing of the respective devices.

[0052] These objects are fulfilled by the present technology.

[0053] The invention is defined by the appended claims.

[0054] According to one aspect of the present technology, a user formable element is provided for a patient interface. Such patient interface is preferably adapted and suitable for treatment of disordered breathing sleep using air pressure and for delivering air, particularly pressurized air, to a patient's airway. For example, the user formable element may be a seal forming structure. In one embodiment, the user formable element comprises, in particular, a section of a thermo-formable material. That is a material having a relatively low softening or transition temperature, such as polycaprolactane (PCL). Such an element can then be fitted by a user to the individual physiological facial characteristics to fit the patient interface or at least the user formable element to the individual patient. This may provide more comfortable seating and/or improved sealing of the interface on a patient's face, particularly during therapy of sleep disordered breathing using air pressure.

[0055] The shaping of the formable material is intended to occur following known procedures for such materials, such as heating in warm water, by infrared radiation, microwave radiation or other means of heating available in the user's household.

[0056] The thermo-formable material has properties enabling it to soften when exposed to increased temperatures, such as 40°C-100°C, and to solidify again as the temperature drops below a certain threshold. The transition temperature of the material may be sufficiently low so that sustained contact with the patient's face during the forming stage is advantageously possible without, e.g., causing pain or skin damage due to the material's temperature.

[0057] The user may heat either only the user formable element, such as the seal forming structure, and/or the entire mask system, then apply the heated section to his or her face so that it adapts to the physical characteristics. Finally, the user formable element is cooled again so that it retains the new, customized shape which now effectively corresponds to the patient's physiognomy. In this context, it is to be noted that the material is not necessarily actively cooled, e.g. by commonly known measures, such as by immersion in a liquid or a gas of lower temperature, or by exposure to a cooling air flow or the like. The temperature drop below the transition temperature threshold may also occur due to passive cooling, i.e. passive heat dissipation due to the material cooling off by itself due to heat dissipation into ambient.

[0058] However, the material of user formable element, for example, PCL, may not suffice as a material for the seal forming structure, due to, for example, its handling issues, lack of softness, lack of elasticity, etc. In a preferred embodiment of the present technology, it is therefore intended to combine the user formable element with other materials, such a polycarbonate, polyamide, polybutylene terephthalate, and others. Furthermore, other known soft and elastic materials, such as silicone, thermoplastic elastomers, foams, and others, may also be used to produce the seal forming structure. The present technology may therefore improve the fit and functioning of existing respiratory masks and add the benefit of providing the user with means for adaptation to his individual physiognomy.

[0059] The advantages of the present technology include an improved mask fit and seal, improved comfort through individualized fit, reduction of pressure points and pressure sores. Furthermore, with the manufacturing methods disclosed herein, the devices may also be produced in an efficient manner.

[0060] The present technology is generally directed towards providing medical devices used in the diagnosis, amelioration, treatment, or prevention of respiratory disorders having one or more of improved comfort, cost, efficacy, ease of use and manufacturability.

[0061] A first aspect of the present technology relates to apparatus used in the diagnosis, amelioration, treatment or prevention of a respiratory disorder.

[0062] Another aspect of the present technology relates to methods used in the diagnosis, amelioration, treatment or prevention of a respiratory disorder.

[0063] An aspect of certain forms of the present technology is to provide methods and/or apparatus that improve the compliance of patients with respiratory therapy.

[0064] An aspect of one form of the present technology is a method of manufacturing apparatus.

[0065] An aspect of one form of the present technology is a portable RPT device that may be carried by a person, e.g., around the home of the person.

[0066] An aspect of one form of the present technology is a patient interface that may be washed in a home of a patient, e.g., in soapy water, without requiring specialised cleaning equipment. An aspect of one form of the present technology is a humidifier tank that may be washed in a home of a patient, e.g., in soapy water, without requiring specialised cleaning equipment.

[0067] Of course, portions of the aspects may form sub-aspects of the present technology. Also, various ones of the sub-aspects and/or aspects may be combined in various manners and also constitute additional aspects or sub-aspects of the present technology.

[0068] While it is preferred that the first section includes a thermoformable material and this embodiment is discussed in greater detail below, it is to be understood that the present technology is not limited to such materials. Instead, other user-formable materials may also be used - instead of applying heat to the user-formable material, it may also be possible that other measures are applied thereto to bring the material in a transition state (i.e. a state where the user may deform it). Non-limiting examples of bringing the material to the transition state include the application of pressure, force, humidity, voltage or current.

[0069] In other words, there are different amounts (i.e. areas) of thermoformable material in different cross sections along the perimeter. Such amounts may vary in thickness, width, or cross-sectional geometry.

[0070] Other features of the technology will be apparent from consideration of the information contained in the following detailed description, abstract, drawings and claims.

3 BRIEF DESCRIPTION OF THE DRAWINGS

[0071] The present technology is illustrated by way of example, and not by way of limitation, in the figures of the accompanying drawings, in which like reference numerals refer to similar elements including:

3.1 TREATMENT SYSTEMS

[0072]

Fig. 1a shows a system including a patient 1000 wearing a patient interface 3000, in the form of a nasal pillows, receiving a supply of air at positive pressure from an RPT device 4000. Air from the RPT device is humidified in a humidifier 5000. and passes along an air circuit 4170 to the patient 1000. A bed partner 1100 is also shown.

Fig. 1b shows a system including a patient 1000 wearing a patient interface 3000, in the form of a nasal mask, receiving a supply of air at positive pressure from an RPT device 4000. Air from the RPT device is humidified in a humidifier 5000, and passes along an air circuit 4170 to the patient 1000.

Fig. 1c shows a system including a patient 1000 wearing a patient interface 3000, in the form of a full-face mask, receiving a supply of air at positive pressure from an RPT device 4000. Air from the RPT device is humidified in a humidifier 5000, and passes along an air circuit 4170 to the patient 1000.

3.2 RESPIRATORY SYSTEM AND FACIAL ANATOMY

[0073]

Fig. 2a shows an overview of a human respiratory system including the nasal and oral cavities, the larynx, vocal folds, oesophagus, trachea, bronchus, lung, alveolar sacs, heart and diaphragm.

Fig. 2b shows a view of a human upper airway including the nasal cavity, nasal bone, lateral nasal cartilage, greater alar cartilage, nostril, lip superior, lip inferior, larynx, hard palate, soft palate, oropharynx, tongue, epiglottis, vocal folds, oesophagus and trachea.

Fig. 2c is a front view of a face with several features of surface anatomy identified including the lip superior, upper vermilion, lower vermilion, lip inferior, mouth width, endocanthion, a nasal ala, nasolabial sulcus and cheilion. Also indicated are the directions superior, inferior, radially inward and radially outward.

Fig. 2d is a side view of a head with several features of surface anatomy identified including glabella, sellion, pronasale, subnasale, lip superior, lip inferior, supramenton, nasal ridge, alar crest point, otobasion superior and otobasion inferior. Also indicated are the directions superior & inferior, and anterior & posterior.

Fig. 2e is a further side view of a head. The approximate locations of the Frankfort horizontal and nasolabial angle are indicated. The coronal plane is also indicated.

Fig. 2f shows a base view of a nose with several features identified including naso-labial sulcus, lip inferior, upper Vermilion, naris, subnasale, columella, pronasale, the major axis of a naris and the sagittal plane.

Fig. 2g shows a side view of the superficial features of a nose.

Fig. 2h shows subcutaneal structures of the nose, including lateral cartilage, septum cartilage, greater alar cartilage, lesser alar cartilage, sesamoid cartilage, nasal bone, epidermis, adipose tissue, frontal process of the maxilla and fibrofatty tissue.

Fig. 2i shows a medial dissection of a nose, approximately several millimeters from a sagittal plane, amongst other things showing the septum cartilage and medial crus of greater alar cartilage.

Fig. 2j shows a front view of the bones of a skull including the frontal, nasal and zygomatic bones. Nasal concha are indicated, as are the maxilla, and mandible.

Fig. 2k shows a lateral view of a skull with the outline of the surface of a head, as well as several muscles. The following bones are shown: frontal, sphenoid, nasal, zygomatic, maxilla, mandible, parietal, temporal and occipital. The mental protuberance is indicated. The following muscles are shown: digastricus, masseter, sternocleidomastoid and trapezius.

Fig. 2i shows an anterolateral view of a nose.

3.3 PATIENT INTERFACE. SEAL FORMING STRUCTURE AND METHOD OF MANUFACTURE

[0074]

Fig. 3a shows a patient interface in the form of a nasal mask in accordance with one form of the present technology.

Figure 4a shows a cross sectional view of patient interface in accordance with one form of the present technology.

Figure 4b shows an enlarged detail of the patient interface of Figure 4a.

Figures 5a-5c show various aspects of patient interfaces in accordance with forms of the present technology.

Figures 6a-6g show still different aspects of patient interfaces in accordance with forms of the present technology.

Figures 7a-7c show still further aspects of patient interfaces in accordance with forms of the present technology.

Figures 8a and 8b show still further aspects of patient interfaces in accordance with forms of the present technology.

Figure 9a shows a molding tool for manufacture of a patient interface in accordance with the present technology.

Figure 9b shows a patient interface manufactured with the tool depicted in Figure 9a.

4 DETAILED DESCRIPTION OF EXAMPLES OF THE TECHNOLOGY

[0075] Before the present technology is described in further detail, it is to be understood that the technology is not limited to the particular examples described herein, which may vary. It is also to be understood that the terminology used in this disclosure is for the purpose of describing only the particular examples discussed herein, and is not intended to be limiting.

[0076] The following description is provided in relation to various examples which may share one or more common characteristics and/or features. It is to be understood that one or more features of any one example may be combinable with one or more features of another example or other examples. In addition, any single feature or combination of features in any of the examples may constitute a further example.

4.1 THERAPY

[0077] In one form, the present technology comprises a method for treating a respiratory disorder comprising the step of applying positive pressure to the entrance of the airways of a patient 1000.

[0078] In certain examples of the present technology, a supply of air at positive pressure is provided to the nasal passages of the patient via one or both nares.

[0079] In certain examples of the present technology, mouth breathing is limited, restricted or prevented.

4.2 TREATMENT SYSTEMS

[0080] In one form, the present technology comprises an apparatus or device for treating a respiratory disorder. The apparatus or device may comprise an RPT device 4000 for supplying pressurised air to the patient 1000 via an air circuit 4170 to a patient interface 3000.

4.3 PATIENT INTERFACE

[0081] A non-invasive patient interface 3000 in accordance with one aspect of the present technology comprises the following functional aspects: a seal-forming structure 3100, a plenum chamber 3200, a positioning and stabilising structure 3300 and one form of connection port 3600 for connection to air circuit 4170. In some forms a functional aspect may be provided by one or more physical components. In some forms, one physical component may provide one or more functional aspects. In use the seal-forming structure 3100 is arranged to surround an entrance to the airways of the patient so as to facilitate the supply of air at positive pressure to the airways.

4.3.1 Seal-forming structure

[0082] In one form of the present technology, a seal-forming structure 3100 provides a seal-forming surface, and may additionally provide a cushioning function.

[0083] A seal-forming structure 3100 in accordance with the present technology may be constructed from a soft, flexible, resilient material such as silicone.

[0084] In one form, the seal-forming structure 3100 comprises a sealing flange 3110 and a support flange 3120. The sealing flange 3110 comprises a relatively thin member with a thickness of less than about 1mm. for example about 0.25mm to about 0.45mm. that extends around the perimeter 3210 of the plenum chamber 3200. Support flange 3120 may be relatively thicker than the sealing flange 3110. The support flange 3120 is disposed between the sealing flange 3110 and the marginal edge 3220 of the plenum chamber 3200, and extends at least part of the way around the perimeter 3210. The support flange 3120 is or includes a spring-like element and functions to support the sealing flange 3110 from buckling in use. In use the sealing flange 3110 can readily respond to system pressure in the plenum chamber 3200 acting on its underside to urge it into tight sealing engagement with the face.

[0085] In one form the seal-forming portion of the non-invasive patient interface 3000 comprises a pair of nasal puffs, or nasal pillows, each nasal puff or nasal pillow being constructed and arranged to form a seal with a respective naris of the nose of a patient.

[0086] Nasal pillows in accordance with an aspect of the present technology include: a frusto-cone, at least a portion of which forms a seal on an underside of the patient's nose, a stalk, a flexible region on the underside of the frusto-cone and connecting the frusto-cone to the stalk. In addition, the structure to which the nasal pillow of the present technology is connected includes a flexible region adjacent the base of the stalk. The flexible regions can act in concert to facilitate a universal joint structure that is accommodating of relative movement both displacement and angular of the frusto-cone and the structure to which the nasal pillow is connected. For example, the frusto-cone may be axially displaced towards the structure to which the stalk is connected.

[0087] In one form, the non-invasive patient interface 3000 comprises a seal-forming portion that forms a seal in use on an upper lip region (that is, the *lip superior*) of the patient's face.

[0088] In one form the non-invasive patient interface 3000 comprises a seal-forming portion that forms a seal in use on a chin-region of the patient's face.

4.3.2 Plenum chamber

[0089] The plenum chamber 3200 has a perimeter 3210 that is shaped to be complementary to the surface contour of the face of an average person in the region where a seal will form in use. In use, a marginal edge 3220 of the plenum chamber 3200 is positioned in close proximity to an adjacent surface of the face. Actual contact with the face is provided by the seal-forming structure 3100. The seal-forming structure 3100 may extend in use about the entire perimeter 3210 of the plenum chamber 3200.

4.3.3 Positioning and stabilising structure 3300

[0090] The seal-forming portion 3100 of the patient interface 3000 of the present technology may be held in sealing position in use by the positioning and stabilising structure 3300.

[0091] In one form of the present technology, a positioning and stabilising structure 3300 is provided that is configured in a manner consistent with being worn by a patient while sleeping. In one example the positioning and stabilising

structure 3300 has a low profile, or cross-sectional thickness, to reduce the perceived or actual bulk of the apparatus. In one example, the positioning and stabilising structure 3300 comprises at least one strap having a rectangular cross-section. In one example the positioning and stabilising structure 3300 comprises at least one flat strap.

[0092] In one form of the present technology, a positioning and stabilising structure 3300 comprises a strap constructed from a laminate of a fabric patient-contacting layer, a foam inner layer and a fabric outer layer. In one form, the foam is porous to allow moisture, (e.g., sweat), to pass through the strap. In one form, the fabric outer layer comprises loop material to engage with a hook material portion.

[0093] In certain forms of the present technology, a positioning and stabilising structure 3300 comprises a strap that is extensible, e.g. resiliently extensible. For example the strap may be configured in use to be in tension, and to direct a force to draw a cushion into sealing contact with a portion of a patient's face. In an example the strap may be configured as a tie.

[0094] In certain forms of the present technology, a positioning and stabilising structure 3300 comprises a strap that is bendable and e.g. non-rigid. An advantage of this aspect is that the strap is more comfortable for a patient to lie upon while the patient is sleeping.

4.3.4 Vent

[0095] In one form, the patient interface 3000 includes a vent 3400 constructed and arranged to allow for the washout of exhaled carbon dioxide.

[0096] One form of vent 3400 in accordance with the present technology comprises a plurality of holes, for example, about 20 to about 80 holes, or about 40 to about 60 holes, or about 45 to about 55 holes.

[0097] The vent 3400 may be located in the plenum chamber 3200. Alternatively, the vent 3400 is located in a decoupling structure 3500, e.g., a swivel 3510.

4.3.5 Decoupling structure(s)

[0098] In one form the patient interface 3000 includes at least one decoupling structure 3500, for example, a swivel 3510 or a ball and socket 3520.

4.3.6 Connection port

[0099] Connection port 3600 allows for connection to the air circuit 4170.

4.3.7 Forehead support

[0100] In one form, the patient interface 3000 includes a forehead support 3700.

4.3.8 Anti-asphyxia valve

[0101] In one form, the patient interface 3000 includes an anti-asphyxia valve 3800.

4.3.9 Ports

[0102] In one form of the present technology, a patient interface 3000 includes one or more ports that allow access to the volume within the plenum chamber 3200. In one form this allows a clinician to supply supplemental oxygen. In one form, this allows for the direct measurement of a property of gases within the plenum chamber 3200, such as the pressure.

4.4 FURTHER DESCRIPTION OF EXAMPLES OF THE PATIENT INTERFACE, THE SEAL FORMING STRUCTURE AND MANUFACTURING METHODS

[0103] Figure 5a shows one aspect in accordance with the present technology. In this aspect of the present technology, a seal forming structure 3100 of a patient interface 3000 is provided. This seal forming structure 3100 may be a user formable pad preferably consisting of or comprising a thermo-formable material. In accordance with the center section/middle Figure of Figure 5a, e.g., heat (depicted as wavy lines) may be applied to seal forming structure 3100, such that this seal forming structure 3100 softens. In this regard, it is pointed out that the present specification is in particular and preferably directed to a thermo-formable structure. However, even though the embodiments are directed thereto, the skilled person will understand that the present technology may also be employed be means of other user formable

structures. The seal forming structure 3100 may then, in this softened state, be applied to a patient's face (see right depiction in Figure 5a) and assume the approximate shape of the patient's face. When the seal forming structure 3100 cools down again, it will remain in this shape. Thereby, an individual or customized shape and thus fit of the seal forming structure on this particular user's face is achieved.

[0104] To achieve this, the seal forming structure 3100 may have a thermo-formable section 3150 (see, e.g., Figure 4a and 4b). This section may be made of a material having a specific transition temperature. Below this transition temperature, which may also be referred to as a melting temperature or as a softening point, the material maintains its shape. Above this transition temperature, the material may be deformed. Typically, this transition temperature is above the temperature a patient interface 3000 typically assumes in use. That is, this transition temperature may be, e.g., in the range of 40°C-100°C. Lower temperatures of this range, such as 40°C to 60°C may be preferred to avoid to allow contact with a user's skin for customization without causing pain or skin damage to the face due to the material's temperature. As discussed, a user may heat the seal forming structure 3100 (either on its own or with the remainder of the patient interface 3000) above the transition temperature, e.g., by means of warm water, infrared radiation, microwave radiation or other means of heating available in the user's household and then deform the seal forming structure 3100. preferably by applying it to or pressing it on his or her face. When the seal forming structure 3100 then cools down again below the transition temperature, it will maintain the respective shape. As a result the seal forming structure may better fit to the patient's physiognomy of the face. Thus, a better sealing may be achieved and a more comfortable fit of the patient interface 3000 to the user.

[0105] This may be achieved in various embodiments of the present technology. Turning generally to Figure 4a, a patient interface 3000 typically comprises a shell 3250. If the patient interface 3000 is realized as a mask, this shell 3250 may also be referred to as a chassis or as a mask chassis. The shell 3250 may be formed from a relatively rigid material, such as polycarbonate. However, other materials, such as polyamide, polybutylene terephthalate and/or others may also be used for this embodiment and the other embodiments of the present technology. Typically, the patient interface 3000 also comprises a connection port 3600 for connection to a breathing gas line. The connection port 3600 may either be adapted for direct connection of a breathing gas line or for indirect connection to such a breathing gas line, e.g., by means of a swivel elbow. The patient interface 3000 may also comprise a vent 3400 including a plurality of apertures for washing out a exhaled air. Furthermore, the embodiment depicted in Figures 4a and 4b also comprises a seal forming structure 3100, such as a pad. This seal forming structure 3100 includes the thermo-formable section 3150. The seal forming structure 3100 also comprises a second portion 3160 of another material. In the embodiment depicted in Figures 4a and 4b, this section of another material completely surrounds or encloses the thermo-formable section 3150, which may therefore also be referred to, in this embodiment, as a thermo-formable core section. As depicted, the second section 3160 is adapted to come into contact with a patient's face during use of the patient interface 3100. Typically, the second section 3160 is therefore preferably formed of a skin-friendly and/or seal enhancing material, such as, for example, silicon. In the depicted embodiment, the patient interface also comprises a carrier portion 3252 or cushion structure. One end of the carrier portion 3252 may be T-shaped. The carrier portion 3252 may be formed integrally with shell 3250. However, alternatively, carrier portion 3252 may also be formed from another material than shell 3250. For example, carrier portion 3252 may also be formed of a material being more resilient then shell 3252 to allow, e.g., for bending of the carrier portion 3252. As depicted in Figure 4b, carrier portion 3252 may have a T-shaped end section - also see Figures 5b and 5c being sections along line A-A of Figure 5a. Such an end section may include a platform region 3254 (preferably the T-beam of the T-shape cross sectional structure), which may be generally flat. The seal forming structure 3100 may be applied to this platform region 3254, e.g., by means of an adhesive such as an adhesive strip 3190. In this regard, seal forming structure 3100 may also have a substantially flat end section to allow for easy connection to platform region 3254 by means of adhesive 3190.

[0106] Figures 5b and 5c depict the cross-section of different embodiments. The main difference of the two embodiments depicted in Figures 5b and 5c resides in the fact that the seal forming structure 3100 of the embodiment in Figure 5c includes a sealing flange 3110. This sealing flange 3110 may also be referred to as a sealing membrane or as a sealing lip. This sealing flange 3110 is a structure comprising, in a cross sectional view as depicted in Figure 5c, an elongation which is substantially larger than its thickness. In this regard, the sealing flange 3110 may also be referred to as being a thin section. The sealing flange 3110 may allow for a particularly safe and comfortable seal between the patient interface and the user's face. As depicted, the sealing flange 3110 is formed integrally with the second section 3160. That is, in other words, the sealing flange 3110 is formed as a part of this second section 3160.

[0107] As discussed, in the embodiments depicted in Figures 4 and 5, the thermo-formable section 3150 may be completely enclosed by, surrounded by or embedded within the second section 3160. In other words only the second material of section 3160 of seal forming structure 3100 may be exposed to the outside. In again other words, a patient using this patient interface may only come into contact with second section 3160, but not with the thermo-formable section 3150. This may be beneficial, as the patient, when handling seal forming structure 3100, would only come into contact with the section 3160, which may be generally formed of skin-friendly material. This may broaden the choice of thermo-formable materials to be used for thermo-formable section 3150. Furthermore, it may also give the patient a

more comfortable feel of the seal forming structure 3100, as the patient only comes into contact with materials, which are already known to him. In particular, this may also improve patient compliance.

[0108] Still further aspects of the embodiment depicted in Figures 5a to Figures 5c may include that the seal forming structure 3100, e.g., a user formable pad, may be applied to a carrier portion 3252, that is a carrier system, preferably by means of adhesive. The shaping of the seal forming structure 3100 will transfer to the carrier system by deforming the respective component. Prior to forming, the seal forming structure 3100 may be substantially flat and shaped suitable to correspond to the carrier portion 3252. This may also include the additional advantages of the respective seal forming structure 3100 being replaceable and enabling an upgrade of existing patient interfaces.

[0109] The present technology, however, is not limited to the embodiment depicted in Figures 4 and 5. Another preferred embodiment of the present technology is also depicted in Figures 6a to 6g. Figure 6a again depicts the general outline of a patient interface 3000 including a shell or chassis 3250 and a seal forming structure 3100. Again, a connection portion 3600 for connection of a tube or an elbow is included. Figure 6b depicts a cross-sectional view along line A-A of Figure 6a. It should be noted that Figures 6a and 6b (as well as Figures 6c to 6e) depict a patient interface 3000 (or parts/details thereof) during the manufacturing process, that is before the patient interface is ready for use by a patient. In particular, the seal forming structure 3100 is not yet completely formed in these Figures 6a to 6e. To the contrary, in these Figures, the patient interface 3000 to be formed includes the shell 3250 and the thermo-formable section 3250 of seal forming structure 3100. The shell 3250 and the thermo-formable section 3150 may be connected to each other in a variety of ways, as depicted in Figures 6c to 6e. According to Figure 6c, there may be provided an interface 3256 shaped to support a chemical bond between the thermo-formable section 3150 and the shell 3250, such interface may be a projection. In the embodiments discussed in conjunction to Figures 6a to 6g, the respective section of the shell 3250 may also be referred to as a substrate, onto which the thermo-formable section 3150 is applied. According to Figure 6d, there may also be provided a molded mechanical interlock 3258 for connection of the shell or substrate 3250 and the thermo-formable section 3150. This may be achieved by provision of a grid like structure comprising holes between structural sections 3258. Furthermore, the tool sections may also be connected to each other by means of a mechanical interlock 3260, such as a snap fit, as depicted in Figure 6e. However, as will be apparent, the skilled person may also use other means to interconnect the substrate 3250 and the thermo-formable section 3150.

[0110] As depicted (see, e.g., Figure 6b) the thermo-formable section 3150 may have a generally elongated shape. That is, in a cross sectional view, one dimension of the thermo-formable section may be substantially larger than another dimension. In this regard, the thermo-formable section 3150 may be thin. In other words, the thermo-formable section 3150 may also be referred to as a fin 3150.

[0111] In other words, and as described above and below, the Fig. 6a shows a frontal view of a mask chassis with a thermoformable fin around the entire circumference, Fig. 6b a cross section of same. Figs 6c to 6e illustrate different details of means of connection between chassis and thermoformable fin. Fig 6f shows a chassis and thermoformable fin (which may use any of the principles, e.g. as shown in and discussed with regard to Figs. 6c to 6e) overmoulded in silicone to form a mask cushion. Fig 6g shows a detail of a cross sections of the thermoformable fin deformed after the adaption process.

[0112] As discussed, Figures 6a-6e depict the patient interface 3000 in an intermediate state of the production process. In addition to the structures discussed above in conjunction to Figures 6a-6e, a second material is applied to the patient interface 3000 to form the second section 3160 of seal forming structure 3100, here not simply a pad but a cushion-structure. In this context, it should be noted that the general discussion of a pad includes reference to a cushion and vice-versa. Again, typically a material suitable for skin contact, that is skin-friendly material may be used for the material of the second section 3160. As an example, silicon may be used.

[0113] Generally, this second section 3160 of seal forming structure 3100 may be applied to the other parts by means of over molding. That is, the two component part depicted in Figures 6a-6e may be inserted into a tool for over molding and may be over molded, e.g., with silicon, to form the seal forming structure 3100, such as the pad or cushion. Thus, a three component (3K) patient interface would be formed with a thermo-formable element.

[0114] After formation of the patient interface 3000 in such a way, the user may heat up the patient interface 3000 to soften the thermo-formable section or thermo-formable element 3150 and apply it to the face so that this element may take shape. The thermo-formable section, that is, in this embodiment, the thermo-formable fin, may also be (pre-)shaped to match a patient's generalized physiognomy quite closely, thereby limiting the amount of shaping required to achieve the adaptation to individual features. As indicated above, Fig. 6f shows a preferred structure before heating and customization while Fig. 6g shows the same preferred structure after thermoforming.

[0115] Figures 6f and 6g show two cross sectional views along, e.g., lines A-A and B-B (which are basically identical cross sections but simply refer to different points in time, i.e. one before A-A and one after thermoforming B-B) of Figure 6a, however, only after over-molding with a second material. While Fig. 6a shows the structure before thermoforming, Fig. 6b shows the structure after shaping by a patient has taken place. As will be apparent, the part of the thermo-formable section 3150 in Figure 6g has been deformed vis-à-vis the former state of the thermo-formable section 3150 as seen in Figure 6f. While the part of the thermo-formable section 3150 in Figure 6f has a thin, fin-like shape, the part

of the thermo-formable section 3150 in Figure 6g has been compressed to adopt a more bulky cross-sectional shape. That is, in other words, the amount of forming required may not be uniform around the perimeter of the patient interface. Instead, there may be areas with more deformation and/or deflection and other areas with less deformation and/or deflection.

[0116] Furthermore, Figures 6f and 6g also depict the seal forming structure 3100 to comprise both a sealing flange 3110 and a support flange 3120. These may be formed integrally with the second section 3160. In other words, these sections may also be referred to be part of the second section 3100, that is, in other words, the second section 3160 comprises the sealing flange 3110 and the support flange 3120. However, the skilled person will readily understand that the provision of sealing flange, e.g. membrane 3110 and undercushion 3120, in this embodiment is only exemplary - that is, the skilled person may also not include these features in the present embodiment or may, alternatively, include the features of a sealing flange 3110 and a support flange 3120 in the other embodiments, such as the embodiment depicted in Figure 4a to 5b.

[0117] As is also depicted in Figures 6f and 6g, the thermo-formable material 3150 may be completely surrounded by other material. That is, all the surface sections of the thermo-formable section 3150 not being in contact with substrate 3250 are in contact with second section 3160 of seal forming structure 3100. In other words, no portion of the thermo-formable section 3150 is exposed to ambient, such that the user will not come into contact with thermo-formable section 3150, such that the user only comes to contact with material he is used tom, which may improve, e.g., user compliance. In other words, as depicted and discussed, part of the thermo-formable material may not be covered or surrounded by second material or section 3160 of seal forming structure 3100 but in contact with and covered by substrate 3250.

[0118] Figures 7a to 7c depict yet another embodiment of the present technology. Again, Figures 7a and 7b depict the patient interface 3100 before the final step of over molding and Figure 7c depicts the patient interface 3000 after over-molding has taken place. According to Figures 7a, the patient interface 3000 to be formed includes a shell or chassis 3250 with a connection port 3600 (also see the sectional view of Figure 7b). Furthermore, the patient interface 3000 again comprises a thermo-formable section 3150. The thermo-formable section 3150 includes a perimeter section 3152 and a plurality of leg members or web portions 3154 connecting the perimeter section 3152 to the mask shell 3250. In the depicted embodiment, there are provided three web portions 3154, however, the skilled person will understand that also a different number of web portions 3154, such as 2, 4, 5 or more web portions may be provided. The web portions 3154 are preferably also made of the thermo-formable material, but may also be made of another material.

[0119] Figure 7c again depicts a cross sectional view along line A-A of Figure 7a after over molding has taken place. As will be apparent, this embodiment, too, comprises a seal forming structure 3100 including a thermo-formable section 3150 and a second section 3160. As discussed above, the second section 3160 may include a sealing flange 3110 and may include a support flange 3120. Again, the patient interface may be formed in such a way that no section of the thermo-formable section 3150 is exposed to ambient, but the thermo-formable section 3150 is completely enclosed by the shell 3250 (at the connection points) and by the second section 3160 of the seal forming structure 3100.

[0120] In this embodiment, the thermo-formable section is not connected or bonded to the shell 3250 (or substrate) around the entire perimeter, but only in selected locations, e.g., at the web portions 3154. This may improve the forming range of the user formable seal forming structure 3100. In other words, the thermo-formable section 3150, which may also be fin-shaped, may protrude further away from the shell 3250, thereby adding additional degrees of freedom to the shaping. As discussed, the perimeter section 3150 may be in the shape of a fin, however, it may also take another shape and be referred to as a frame or stiffener portion 3152. In the cross sectional view of Figure 7b, it can be seen that in the lower half of this cross sectional view, there is no direct connection between the thermo-formable section 3150 and the shell or substrate 3250. Instead, the gap G of Figure 7b is filled with the material of the second section 3160, such as silicon, during the over molding process, resulting in a larger extension of the second section 3160 contributing to a larger adjustment range.

[0121] Figures 8a and 8b show another embodiment of the present technology, Figure 8b being an enlarged view of a detail of Figure 8a. Again, the patient interface 3000 of this embodiment includes a shell or chassis 3250 with a connection port 3600. Furthermore, the patient interface 3000 also includes a seal forming structure 3100, which may include a sealing flange 3110 and which may also include a support flange 3120. as discussed above (although these structures do not necessarily need to be provided).

[0122] Furthermore, the seal forming structure 3100 includes a pocket or groove 3130 adapted for receiving a thermo-formable section 3150. Generally, the shell 3250 and the seal forming structure 3100 define together a plenum chamber 3200. During use, seal forming structure 3100 and shell 3250 limit, together with a patient's face, a certain space, that is the plenum chamber 3200. This section may also be referred to as the interior of the patient interface. Conversely thereto, there is also an exterior 3270 of the patient interface 3000. That is the space other the space delimited, during use, by the patient interface 3000 and the patient. Preferably, the groove or pocket 3130 is only accessibly from the patient interface's outside 3270. In other words, the pocket or groove 3130 is provided on the outside 3250 of the patient interface 3000. As depicted in Figure 8b the groove 3130 may be provided with at least one undercut 3132 and preferably a plurality of undercuts 3132, that is. e.g., two undercuts 3132, forming a mechanical interlock feature to prevent the

thermo-formable section 3135 from coming loose during forming. Alternatively or in addition, a chemical bond can be formed between the thermo-formable section 3150 and the groove 3130.

[0123] For production of this embodiment of the present technology, the shell or chassis 3250 and the section 3160 of the seal forming structure 3100 are molded in a two component molding process in such a way that the seal forming structure 3100 includes the groove or pocket 3130 into which thermo-formable material is introduced at a second stage after the molding, e.g., by means of potting and/or dosing processes. Again, the section 3160 of the sealing structure may be silicon and the thermo-formable material may be polycaprolactane (PCL).

[0124] This embodiment allows for an alternative manufacturing process, which is particularly easy and allows a simple introduction of the thermo-formable section 3130.

[0125] A still further embodiment of a patient interface 3000 of the present technology, as well as a corresponding manufacturing process, are depicted in Figures 9a and 9b. Figure 9a depicts a manufacturing tool, such as a molding tool with two sections A and B. One of the two sections A and B is a movable section, while the other section is a fixed section of the tool. For example, section B may be a fixed tool section and section A may be a movable tool section. In this tool, there is placed an insert for a shell 3250 of the patient interface 3000 having a connection portion 3600. Furthermore, there is also placed an insert for the seal forming structure 3100 in this tool. Furthermore, an insert of thermo-formable material 3150 is also placed in this tool. Near and around the insert for the thermo-formable section 3150, there is provided a gap of cavity 3174. In particular, the insert for the seal forming structure 3100 may include a pocket or cavity 3130 into which the insert of thermo-formable material 3150 is placed.

[0126] The thermo-formable material 3150 may be cast, pointed or dosed or molded into the groove 3130 or assembled as a separate component thereof. The resulting two-component-structure may be inserted into the tool A-B, together with the insert for the shell or chassis 3250. All these components may then be over molded in another step to complete the assembly. That is, a further material, such as silicon, is introduced to fill the cavity 3174 to connect the components with each other.

[0127] A resulting patient interface 3000 is depicted in cross section in Figure 9b. Again, this patient interface includes a shell or chassis 3250 with a connection port 3600, as well as a seal forming structure 3100, which may (or may not) comprise at least one of a sealing flange 3110 and a support flange 3120. Furthermore, the seal forming structure 3100 comprises a thermo-formable section 3150 and a second section 3160 of another material. Again, this second section may include the sealing flange 3110 and the support flange 3120. Furthermore, the seal forming structure 3100 of this embodiment also includes a third section 3164 connecting the seal forming structure 3100 to the shell 3250. However, even though the structure 3160 is depicted to be a structure separate from the connecting structure 3164 of seal forming structure 3100, these sections may be made of the same material, such as silicon. However, alternatively, these sections may also be made from different materials.

[0128] This embodiment may allow for still another manufacturing process and a simple molding process, as well as simplicity of tooling.

4.5 GLOSSARY

[0129] For the purposes of the present technology disclosure, in certain forms of the present technology, one or more of the following definitions may apply. In other forms of the present technology, alternative definitions may apply.

4.5.1 General

[0130] *Air:* In certain forms of the present technology, air may be taken to mean atmospheric air, and in other forms of the present technology air may be taken to mean some other combination of breathable gases, e.g. atmospheric air enriched with oxygen.

[0131] *Ambient:* In certain forms of the present technology, the term ambient will be taken to mean (i) external of the treatment system or patient, and (ii) immediately surrounding the treatment system or patient.

[0132] For example, ambient humidity with respect to a humidifier may be the humidity of air immediately surrounding the humidifier, e.g. the humidity in the room where a patient is sleeping. Such ambient humidity may be different to the humidity outside the room where a patient is sleeping.

[0133] In another example, ambient pressure may be the pressure immediately surrounding or external to the body.

[0134] In certain forms, ambient (e.g., acoustic) noise may be considered to be the background noise level in the room where a patient is located, other than for example, noise generated by an RPT device or emanating from a mask or patient interface. Ambient noise may be generated by sources outside the room.

[0135] *Continuous Positive Airway Pressure (CPAP) therapy*: CPAP therapy will be taken to mean the application of a supply of air to an entrance to the airways at a pressure that is continuously positive with respect to atmosphere. The pressure may be approximately constant through a respiratory cycle of a patient. In some forms, the pressure at the entrance to the airways will be slightly higher during exhalation, and slightly lower during inhalation. In some forms, the

pressure will vary between different respiratory cycles of the patient, for example, being increased in response to detection of indications of partial upper airway obstruction, and decreased in the absence of indications of partial upper airway obstruction.

[0136] *Patient*: A person, whether or not they are suffering from a respiratory disease.

[0137] *Automatic Positive Airway Pressure (APAP) therapy*: CPAP therapy in which the treatment pressure is automatically adjustable, e.g. from breath to breath, between minimum and maximum limits, depending on the presence or absence of indications of SDB events.

4.5.2 Aspects of the respiratory cycle

[0138] *Apnea*: According to some definitions, an apnea is said to have occurred when flow falls below a predetermined threshold for a duration, e.g. 10 seconds. An obstructive apnea will be said to have occurred when, despite patient effort, some obstruction of the airway does not allow air to flow. A central apnea will be said to have occurred when an apnea is detected that is due to a reduction in breathing effort, or the absence of breathing effort, despite the airway being patent. A mixed apnea occurs when a reduction or absence of breathing effort coincides with an obstructed airway.

[0139] *Breathing rate*: The rate of spontaneous respiration of a patient, usually measured in breaths per minute.

[0140] *Duty cycle:* The ratio of inhalation time, *Ti* to total breath time, *Ttot.*

[0141] *Effort (breathing)*: Breathing effort will be said to be the work done by a spontaneously breathing person attempting to breathe.

[0142] *Expiratory portion of a breathing cycle:* The period from the start of expiratory flow to the start of inspiratory flow.

[0143] *Flow limitation:* Flow limitation will be taken to be the state of affairs in a patient's respiration where an increase in effort by the patient does not give rise to a corresponding increase in flow. Where flow limitation occurs during an inspiratory portion of the breathing cycle it may be described as inspiratory flow limitation. Where flow limitation occurs during an expiratory portion of the breathing cycle it may be described as expiratory flow limitation.

[0144] Types of flow limited inspiratory waveforms:

(i) *Flattened*: Having a rise followed by a relatively flat portion, followed by a fall.

(ii) *M-shaped*: Having two local peaks, one at the leading edge, and one at the trailing edge, and a relatively flat portion between the two peaks.

(iii) *Chair-shaped:* Having a single local peak, the peak being at the leading edge, followed by a relatively flat portion.

(iv) *Reverse-chair shaped:* Having a relatively flat portion followed by single local peak, the peak being at the trailing edge.

[0145] *Hypopnea*: Preferably, a hypopnea will be taken to be a reduction in flow, but not a cessation of flow. In one form, a hypopnea may be said to have occurred when there is a reduction in flow below a threshold rate for a duration. A central hypopnea will be said to have occurred when a hypopnea is detected that is due to a reduction in breathing effort. In one form in adults, either of the following may be regarded as being hypopneas:

(i) a 30% reduction in patient breathing for at least 10 seconds plus an associated 4% desaturation; or

(ii) a reduction in patient breathing (but less than 50%) for at least 10 seconds, with an associated desaturation of at least 3% or an arousal.

[0146] *Hyperpnea*: An increase in flow to a level higher than normal flow rate.

[0147] *Inspiratory portion of a breathing cycle:* The period from the start of inspiratory flow to the start of expiratory flow will be taken to be the inspiratory portion of a breathing cycle.

[0148] *Patency (airway)*: The degree of the airway being open, or the extent to which the airway is open. A *patent* airway is open. Airway patency may be quantified, for example with a value of one (1) being patent, and a value of zero (0). being closed (obstructed).

[0149] *Positive End-Expiratory Pressure (PEEP):* The pressure above atmosphere in the lungs that exists at the end of expiration.

[0150] *Peak flow* rate *(Qpeak)*: The maximum value of flow rate during the inspiratory portion of the respiratory flow waveform.

[0151] *Respiratory flow* rate, *airflow* rate, *patient airflow* rate, *respiratory airflow* rate *(Qr)*: These synonymous terms may be understood to refer to the RPT device's estimate of respiratory airflow rate, as opposed to "true respiratory flow"

or "true respiratory airflow", which is the actual respiratory flow rate experienced by the patient, usually expressed in litres per minute.

[0152] *Tidal volume (Vt)*: The volume of air inhaled or exhaled during normal breathing, when extra effort is not applied.

[0153] *(inhalation) Time (Ti):* The duration of the inspiratory portion of the respiratory flow rate waveform.

[0154] *(exhalation) Time (Te):* The duration of the expiratory portion of the respiratory flow rate waveform.

[0155] *(total) Time (Ttot)*: The total duration between the start of the inspiratory portion of one respiratory flow rate waveform and the start of the inspiratory portion of the following respiratory flow rate waveform.

[0156] *Typical recent ventilation*: The value of ventilation around which recent values over some predetermined timescale tend to cluster, that is, a measure of the central tendency of the recent values of ventilation.

[0157] *Upper airway obstruction (UAO):* includes both partial and total upper airway obstruction. This may be associated with a state of flow limitation, in which the level of flow increases only slightly or may even decrease as the pressure difference across the upper airway increases (Starling resistor behaviour).

[0158] *Ventilation* (*Vent*): A measure of the total amount of gas being exchanged by the patient's respiratory system. Measures of ventilation may include one or both of inspiratory and expiratory flow, per unit time. When expressed as a volume per minute, this quantity is often referred to as "minute ventilation". Minute ventilation is sometimes given simply as a volume, understood to be the volume per minute.

4.5.3 Anatomy of the face

[0159] *Ala:* the external outer wall or "wing" of each nostril (plural: alar)

[0160] *Alare:* The most lateral point on the nasal *ala.*

[0161] *Alar curvature (or alar crest) point:* The most posterior point in the curved base line of each *ala,* found in the crease formed by the union of the *ala* with the cheek.

[0162] *Auricle:* The whole external visible part of the ear.

[0163] *(nose) Bony framework:* The bony framework of the nose comprises the nasal bones, the frontal process of the maxillae and the nasal part of the frontal bone.

[0164] *(nose) Cartilaginous framework:* The cartilaginous framework of the nose comprises the septal, lateral, major and minor cartilages.

[0165] *Columella:* the strip of skin that separates the nares and which runs from the *pronasale* to the upper lip.

[0166] *Columella angle:* The angle between the line drawn through the midpoint of the nostril aperture and a line drawn perpendicular to the Frankfurt horizontal while intersecting subnasale.

[0167] *Frankfort horizontal plane:* A line extending from the most inferior point of the orbital margin to the left tragion. The tragion is the deepest point in the notch superior to the tragus of the auricle.

[0168] *Glabella:* Located on the soft tissue, the most prominent point in the midsagittal plane of the forehead.

[0169] *Lateral nasal cartilage*: A generally triangular plate of cartilage. Its superior margin is attached to the nasal bone and frontal process of the maxilla, and its inferior margin is connected to the greater alar cartilage.

[0170] *Lip, lower (labrale inferius)*:
Lip, upper (labrale superius):
Greater alar cartilage: A plate of cartilage lying below the lateral nasal cartilage. It is curved around the anterior part of the naris. Its posterior end is connected to the frontal process of the maxilla by a tough fibrous membrane containing three or four minor cartilages of the *ala.*

[0171] *Nares (Nostrils)*: Approximately ellipsoidal apertures forming the entrance to the nasal cavity. The singular form of nares is naris (nostril). The nares are separated by the nasal septum.

[0172] *Naso-labial sulcus or Naso-labial fold*: The skin fold or groove that runs from each side of the nose to the corners of the mouth, separating the cheeks from the upper lip.

[0173] *Naso-labial angle*: The angle between the columella and the upper lip, while intersecting subnasale.

[0174] *Otobasion inferior*: The lowest point of attachment of the auricle to the skin of the face.

[0175] *Otobasion superior*: The highest point of attachment of the auricle to the skin of the face.

[0176] *Pronasale:* the most protruded point or tip of the nose, which can be identified in lateral view of the rest of the portion of the head.

[0177] *Philtrum:* the midline groove that runs from lower border of the nasal septum to the top of the lip in the upper lip region.

[0178] *Pogonion:* Located on the soft tissue, the most anterior midpoint of the chin.

[0179] *Ridge (nasal):* The nasal ridge is the midline prominence of the nose, extending from the Sellion to the Pronasale.

[0180] *Sagittal plane:* A vertical plane that passes from anterior (front) to posterior (rear) dividing the body into right and left halves.

[0181] *Sellion:* Located on the soft tissue, the most concave point overlying the area of the frontonasal suture.

[0182] *Septal cartilage (nasal):* The nasal septal cartilage forms part of the septum and divides the front part of the

nasal cavity.

[0183] *Subalare:* The point at the lower margin of the alar base, where the alar base joins with the skin of the superior (upper) lip.

[0184] *Subnasal point:* Located on the soft tissue, the point at which the columella merges with the upper lip in the midsagittal plane.

[0185] *Supramentale*: The point of greatest concavity in the midline of the lower lip between labrale inferius and soft tissue pogonion

4.5.4 Anatomy of the skull

[0186] *Frontal bone:* The frontal bone includes a large vertical portion, the *squama frontalis,* corresponding to the region known as the forehead.

[0187] *Mandible*: The mandible forms the lower jaw. The mental protuberance is the bony protuberance of the jaw that forms the chin.

[0188] *Maxilla*: The maxilla forms the upper jaw and is located above the mandible and below the orbits. The *frontal process of the maxilla* projects upwards by the side of the nose, and forms part of its lateral boundary.

[0189] *Nasal bones:* The nasal bones are two small oblong bones, varying in size and form in different individuals; they are placed side by side at the middle and upper part of the face, and form, by their junction, the "bridge" of the nose.

[0190] *Nasion:* The intersection of the frontal bone and the two nasal bones, a depressed area directly between the eyes and superior to the bridge of the nose.

[0191] *Occipital bone:* The occipital bone is situated at the back and lower part of the cranium. It includes an oval aperture, the *foramen magnum,* through which the cranial cavity communicates with the vertebral canal. The curved plate behind the foramen magnum is the *squama occipitalis.*

[0192] *Orbit:* The bony cavity in the skull to contain the eyeball.

[0193] *Parietal bones:* The parietal bones are the bones that, when joined together, form the roof and sides of the cranium.

[0194] *Temporal bones:* The temporal bones are situated on the bases and sides of the skull, and support that part of the face known as the temple.

[0195] *Zygomatic bones:* The face includes two zygomatic bones, located in the upper and lateral parts of the face and forming the prominence of the cheek.

4.5.5 Anatomy of the respiratory system

[0196] *Diaphragm:* A sheet of muscle that extends across the bottom of the rib cage. The diaphragm separates the thoracic cavity, containing the heart, lungs and ribs, from the abdominal cavity. As the diaphragm contracts the volume of the thoracic cavity increases and air is drawn into the lungs.

[0197] *Larynx*: The larynx, or voice box houses the vocal folds and connects the inferior part of the pharynx (hypopharynx) with the trachea.

[0198] *Lungs*: The organs of respiration in humans. The conducting zone of the lungs contains the trachea, the bronchi, the bronchioles, and the terminal bronchioles. The respiratory zone contains the respiratory bronchioles, the alveolar ducts, and the alveoli.

[0199] *Nasal cavity:* The nasal cavity (or nasal fossa) is a large air filled space above and behind the nose in the middle of the face. The nasal cavity is divided in two by a vertical fin called the nasal septum. On the sides of the nasal cavity are three horizontal outgrowths called nasal conchae (singular "concha") or turbinates. To the front of the nasal cavity is the nose, while the back blends, via the choanae, into the nasopharynx.

[0200] *Pharynx:* The part of the throat situated immediately inferior to (below) the nasal cavity, and superior to the oesophagus and larynx. The pharynx is conventionally divided into three sections: the nasopharynx (epipharynx) (the nasal part of the pharynx), the oropharynx (mesopharynx) (the oral part of the pharynx), and the laryngopharynx (hypopharynx).

4.5.6 Materials

[0201] *Silicone or Silicone Elastomer*: A synthetic rubber. In this specification, a reference to silicone may be a reference to liquid silicone rubber (LSR) or a compression moulded silicone rubber (CMSR). One form of commercially available LSR is SILASTIC (included in the range of products sold under this trademark). manufactured by Dow Corning. Another manufacturer of LSR is Wacker. Unless otherwise specified to the contrary, an exemplary form of LSR has a Shore A (or Type A) indentation hardness in the range of about 35 to about 45 as measured using ASTM D2240.

[0202] *Polycarbonate*: a typically transparent thermoplastic polymer of Bisphenol-A Carbonate.

4.5.7 Aspects of a patient interface

[0203] *Anti-asphyxia valve (AAV):* The component or sub-assembly of a mask system that, by opening to atmosphere in a failsafe manner, reduces the risk of excessive CO_2 rebreathing by a patient.

[0204] *Elbow:* A conduit that directs an axis of flow of air to change direction through an angle. In one form, the angle may be approximately 90 degrees. In another form, the angle may be less than 90 degrees. The conduit may have an approximately circular cross-section. In another form the conduit may have an oval or a rectangular cross-section.

[0205] *Frame:* Frame will be taken to mean a mask structure that bears the load of tension between two or more points of connection with a headgear. A mask frame may be a non-airtight load bearing structure in the mask. However, some forms of mask frame may also be air-tight.

[0206] *Headgear:* Headgear will be taken to mean a form of positioning and stabilizing structure designed for use on a head. Preferably the headgear comprises a collection of one or more struts, ties and stiffeners configured to locate and retain a patient interface in position on a patient's face for delivery of respiratory therapy. Some ties are formed of a soft, flexible, elastic material such as a laminated composite of foam and fabric.

[0207] *Membrane*: Membrane will be taken to mean a typically thin element that has, preferably, substantially no resistance to bending, but has resistance to being stretched.

[0208] *Plenum chamber*: a mask plenum chamber will be taken to mean a portion of a patient interface having walls enclosing a volume of space, the volume having air therein pressurised above atmospheric pressure in use. A shell may form part of the walls of a mask plenum chamber.

[0209] *Seal*: The noun form ("a seal") will be taken to mean a structure or barrier that intentionally resists the flow of air through the interface of two surfaces. The verb form ("to seal") will be taken to mean to resist a flow of air.

[0210] *Shell*: A shell will be taken to mean a curved, relatively thin structure having bending, tensile and compressive stiffness. For example, a curved structural wall of a mask may be a shell. In some forms, a shell may be faceted. In some forms a shell may be airtight. In some forms a shell may not be airtight.

[0211] *Stiffener*: A stiffener will be taken to mean a structural component designed to increase the bending resistance of another component in at least one direction.

[0212] *Strut:* A strut will be taken to be a structural component designed to increase the compression resistance of another component in at least one direction.

[0213] *Swivel*: (noun) A subassembly of components configured to rotate about a common axis, preferably independently, preferably under low torque. In one form, the swivel may be constructed to rotate through an angle of at least 360 degrees. In another form, the swivel may be constructed to rotate through an angle less than 360 degrees. When used in the context of an air delivery conduit, the sub-assembly of components preferably comprises a matched pair of cylindrical conduits. There may be little or no leak flow of air from the swivel in use.

[0214] *Tie*: A tie will be taken to be a structural component designed to resist tension.

[0215] *Vent*: (noun) the structure that allows an intentional flow of air from an interior of the mask, or conduit to ambient air, e.g. to allow washout of exhaled gases.

4.5.8 Terms used in relation to patient interface

[0216] *Curvature (of a surface)*: A region of a surface having a saddle shape, which curves up in one direction and curves down in a different direction, will be said to have a negative curvature. A region of a surface having a dome shape, which curves the same way in two principal directions, will be said to have a positive curvature. A flat surface will be taken to have zero curvature.

[0217] *Floppy:* A quality of a material, structure or composite that is one or more of:

- Readily conforming to finger pressure.
- Unable to retain its shape when caused to support its own weight.
- Not rigid.
- Able to be stretched or bent elastically with little effort.

[0218] The quality of being floppy may have an associated direction, hence a particular material, structure or composite may be floppy in a first direction, but stiff or rigid in a second direction, for example a second direction that is orthogonal to the first direction.

[0219] *Resilient*: Able to deform substantially elastically, and to release substantially all of the energy upon unloading, within a relatively short period of time such as 1 second.

[0220] *Rigid:* Not readily deforming to finger pressure, and/or the tensions or loads typically encountered when setting up and maintaining a patient interface in sealing relationship with an entrance to a patient's airways.

[0221] *Semi-rigid*: means being sufficiently rigid to not substantially distort under the effects of mechanical forces

typically applied during respiratory pressure therapy.

4.6 OTHER REMARKS

[0222] A portion of the disclosure of this patent document contains material which is subject to copyright protection. The copyright owner has no objection to the facsimile reproduction by anyone of the patent document or the patent disclosure, as it appears in Patent Office patent files or records, but otherwise reserves all copyright rights whatsoever.

[0223] Unless the context clearly dictates otherwise and where a range of values is provided, it is understood that each intervening value, to the tenth of the unit of the lower limit, between the upper and lower limit of that range, and any other stated or intervening value in that stated range is encompassed within the technology. The upper and lower limits of these intervening ranges, which may be independently included in the intervening ranges, are also encompassed within the technology, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either or both of those included limits are also included in the technology.

[0224] Furthermore, where a value or values are stated herein as being implemented as part of the technology, it is understood that such values may be approximated, unless otherwise stated, and such values may be utilized to any suitable significant digit to the extent that a practical technical implementation may permit or require it.

[0225] Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this technology belongs. Although any methods and materials similar or equivalent to those described herein can also be used in the practice or testing of the present technology, a limited number of the exemplary methods and materials are described herein.

[0226] When a particular material is identified as being used to construct a component, obvious alternative materials with similar properties may be used as a substitute. Furthermore, unless specified to the contrary, any and all components herein described are understood to be capable of being manufactured and, as such, may be manufactured together or separately.

[0227] It must be noted that as used herein and in the appended claims, the singular forms "a", "an", and "the" include their plural equivalents, unless the context clearly dictates otherwise.

[0228] The publications discussed herein are provided solely for their disclosure prior to the filing date of the present application. Nothing herein is to be construed as an admission that the present technology is not entitled to antedate such publication by virtue of prior invention. Further, the dates of publication provided may be different from the actual publication dates. which may need to be independently confirmed.

[0229] The terms "comprises" and "comprising" should be interpreted as referring to elements, components, or steps in a non-exclusive manner, indicating that the referenced elements, components, or steps may be present, or utilized, or combined with other elements, components, or steps that are not expressly referenced.

[0230] Any relative term, such as "generally", "substantially", "about", etc. preceding a respective feature should be understood to also encompass the respective features within its exact sense, unless stated otherwise. That is, e.g., "about 3 elements" also encompasses "(exactly) 3 elements" and "generally vertical" also encompasses "vertical".

[0231] The subject headings used in the detailed description are included only for the ease of reference of the reader and should not be used to limit the subject matter found throughout the disclosure or the claims. The subject headings should not be used in construing the scope of the claims or the claim limitations.

[0232] Although the technology herein has been described with reference to particular examples, it is to be understood that these examples are merely illustrative of the principles and applications of the technology. In some instances, the terminology and symbols may imply specific details that are not required to practice the technology. For example, although the terms "first" and "second" may be used, unless otherwise specified, they are not intended to indicate any order but may be utilised to distinguish between distinct elements. Furthermore, although process steps in the methodologies may be described or illustrated in an order, such an ordering is not required. Those skilled in the art will recognize that such ordering may be modified and/or aspects thereof may be conducted concurrently or even synchronously.

[0233] It is therefore to be understood that numerous modifications may be made to the illustrative examples and that other arrangements may be devised without departing from the scope of the technology.

Claims

1. A seal forming structure (3100) for a patient interface (3000) for treatment of sleep disordered breathing using air pressure by delivery of air to a patient's airway,

   wherein the seal forming structure (3100) comprises a first section (3150) of a thermoformable material and a second section (3160) of another material;
   wherein the first section (3150) is at least partially enclosed within the second section (3160);

wherein the material of the second section is a foam material and the second section (3160) comprises a sealing membrane for sealing against the patient's face; and
wherein the thermoformable material has a transition temperature that is in the range of 40°C to 100°C.

2. A seal forming structure (3100) according to claim 1, wherein the first section (3150) is completely enclosed within the second section (3160).

3. A seal forming structure (3100) according to any of the preceding claims, wherein the second section (3160) comprises a planar border section for connection to a platform region (3254).

4. A seal forming structure (3100) according to any of the preceding claims, wherein the second section (3160) comprises the sealing membrane (3110) and a support flange (3120).

5. A seal forming structure (3100) according to any of the preceding claims, wherein the thermorformable material is polycaprolactane (PCL) and wherein the material of the second section (3160) is an elastic material, such as silicone, a thermoplastic elastomer and/or a foam material.

6. A seal forming structure (3100) according to any one of the preceding claims, wherein the second section (3160) includes a groove (3130) for receiving the first section (3150) of thermoformable material.

7. A seal forming structure (3100) according to claim 6, wherein the groove (3130) is located such that the groove (3130) opens to the outside of the patient interface (3000) during use of the patient interface (3000).

8. A patient interface (3000) comprising a seal forming structure (3100) according to any of the preceding claims, wherein the patient interface (3000) further comprises a shell (3250).

9. A patient interface (3000) according to claim 8, wherein the patient interface (3000) further comprises a carrier portion (3252) comprising a platform region (3254), wherein the seal forming structure (3100) is attached to the platform region (3254), e.g. by means of an adhesive (3190).

10. A patient interface (3000) according to claim 8 when not dependent on claim 2, wherein the first section (3150) is, in a cross sectional view, an elongated section, wherein a longitudinal end of the first section (3150) is connected to the shell (3250) and the areas of the first section (3150) not being in contact with the shell (3250) are enclosed by the second section (3260), wherein the longitudinal end of the first section (3150) is connected to the shell (3250) by means of an interface (3256) for a chemical bond, a moulded mechanical interlock (3258) or a mechanical interlock in the form of a snap-fit connection (3260).

11. A patient interface (3000) according to claim 8 when not dependent on claim 2, wherein the first section (3150) comprises a perimeter section (3152) and a plurality of web portions (3154) connecting the perimeter section (3152) to the shell (3250).

12. A patient interface (3000) according to claim 8, wherein the second section (3160) comprises different sub sections (3162, 3164), wherein a first sub section (3162) includes a groove (3130) and wherein the first section (3150) is located in the groove (3130) by means of second sub section (3164) which also connects the seal forming structure (3100) to the shell (3250).

13. Method of manufacturing a patient interface (3000) for treatment of sleep disordered breathing using air pressure by delivery of air to a patient's airway, the method comprising the steps:

connecting a section (3150) of thermoformable material onto a shell insert (3250) preferably by the means referred to in claim 8;
overmoulding at least the section (3150) of thermoformable material with a moulding material (3164) and thereby forming a seal forming structure (3100), the thermoformable material having a transition temperature that is in the range of 40°C to 100°C.

14. Method according to claim 13 further comprising the steps of:

providing the shell insert (3250), an insert for a first sub section (3162) of a seal forming structure (3160), wherein

the first sub section (3162) includes a groove (3130), and the section (3150) of thermoformable material;
locating the provided structures in a tool such that the section (3150) of thermoformable material is located within the groove (3130);
overmoulding the structures with the moulding material (3164), such that the moulding material (3164) connects the shell insert (3250), the first subsection (3162) and the section (3150) of thermoformable material.

15. Method according to claim 13, further comprising the steps of:

providing the shell insert (3250) and a an insert for a section (3160) of a seal forming structure (3100), wherein the insert for a section (3160) of the seal forming structure (3100) includes a groove (3130);
moulding the inserts to one another with the moulding material;
locating the section (3150) of thermoformable material in the groove (3130).

Patentansprüche

1. Dichtungsbildende Struktur (3100) für eine Patientenschnittstelle (3000) zur Behandlung einer schlafbezogenen Atmungsstörung unter Verwendung von Luftdruck durch Zuführen von Luft zu den Atemwegen eines Patienten,

wobei die dichtungsbildende Struktur (3100) einen ersten Abschnitt (3150) aus einem thermoformbaren Material und einen zweiten Abschnitt (3160) aus einem anderen Material umfasst;
wobei der erste Abschnitt (3150) wenigstens teilweise in dem zweiten Abschnitt (3160) eingeschlossen ist;
wobei das Material des zweiten Abschnitts ein Schaumstoffmaterial ist und der zweite Abschnitt (3160) eine Dichtungsmembran zum Abdichten am Gesicht des Patienten umfasst; und
wobei das thermoformbare Material eine Übergangstemperatur im Bereich von 40°C bis 100°C hat.

2. Dichtungsbildende Struktur (3100) nach Anspruch 1, wobei der erste Abschnitt (3150) vollständig in dem zweiten Abschnitt (3160) eingeschlossen ist.

3. Dichtungsbildende Struktur (3100) nach einem der vorherigen Ansprüche, wobei der zweite Abschnitt (3160) einen ebenen Randabschnitt für eine Verbindung mit einer Plattformregion (3254) umfasst.

4. Dichtungsbildende Struktur (3100) nach einem der vorherigen Ansprüche, wobei der zweite Abschnitt (3160) die Dichtungsmembran (3110) und einen Stützflansch (3120) umfasst.

5. Dichtungsbildende Struktur (3100) nach einem der vorherigen Ansprüche, wobei das thermoformbare Material Polycaprolactan (PCL) ist und wobei das Material des zweiten Abschnitts (3160) ein elastisches Material, wie z.B. Silikon, ein thermoplastisches Elastomer und/oder ein Schaumstoffmaterial ist.

6. Dichtungsbildende Struktur (3100) nach einem der vorherigen Ansprüche, wobei der zweite Abschnitt (3160) eine Nut (3130) zur Aufnahme des ersten Abschnitts (3150) aus thermoformbarem Material aufweist.

7. Dichtungsbildende Struktur (3100) nach Anspruch 6, wobei die Nut (3130) so angeordnet ist, dass sich die Nut (3130) beim Verwenden der Patientenschnittstelle (3000) zur Außenseite der Patientenschnittstelle (3000) hin öffnet.

8. Patientenschnittstelle (3000), die eine dichtungsbildende Struktur (3100) nach einem der vorherigen Ansprüche umfasst, wobei die Patientenschnittstelle (3000) ferner eine Schale (3250) umfasst.

9. Patientenschnittstelle (3000) nach Anspruch 8, wobei die Patientenschnittstelle (3000) ferner ein Trägerteil (3252) umfasst, das eine Plattformregion (3254) umfasst, wobei die dichtungsbildende Struktur (3100) an der Plattformregion (3254) befestigt ist, z.B. mit einem Klebstoff (3190).

10. Patientenschnittstelle (3000) nach Anspruch 8, wenn nicht abhängig von Anspruch 2, wobei der erste Abschnitt (3150) in einer Querschnittsansicht ein länglicher Abschnitt ist, wobei ein Längsende des ersten Abschnitts (3150) mit der Schale (3250) verbunden ist und die Bereiche des ersten Abschnitts (3150), die nicht mit der Schale (3250) in Kontakt sind, von dem zweiten Abschnitt (3260) eingeschlossen sind, wobei das Längsende des ersten Abschnitts (3150) mit der Schale (3250) durch eine Schnittstelle (3256) für eine chemische Bindung, eine geformte mechanische Verriegelung (3258) oder eine mechanische Verriegelung in Form einer Schnappverbindung (3260) verbunden ist.

11. Patientenschnittstelle (3000) nach Anspruch 8, wenn nicht abhängig von Anspruch 2, wobei der erste Abschnitt (3150) einen Umfangsabschnitt (3152) und mehrere Stegteile (3154) umfasst, die den Umfangsabschnitt (3152) mit der Schale (3250) verbinden.

12. Patientenschnittstelle (3000) nach Anspruch 8, wobei der zweite Abschnitt (3160) verschiedene Unterabschnitte (3162, 3164) umfasst, wobei ein erster Unterabschnitt (3162) eine Nut (3130) beinhaltet und wobei der erste Abschnitt (3150) in der Nut (3130) mittels eines zweiten Unterabschnitts (3164) angeordnet ist, der auch die dichtungsbildende Struktur (3100) mit der Schale (3250) verbindet.

13. Verfahren zur Herstellung einer Patientenschnittstelle (3000) zur Behandlung einer schlafbezogenen Atmungsstörung unter Verwendung von Luftdruck durch Zuführen von Luft zu den Atemwegen eines Patienten, wobei das Verfahren die folgenden Schritte umfasst:

Verbinden eines Abschnitts (3150) aus thermoformbarem Material mit einem Schaleneinsatz (3250), vorzugsweise mit den in Anspruch 8 genannten Mitteln;
Überformen zumindest des Abschnitts (3150) aus thermoformbarem Material mit einem Formmaterial (3164) und dadurch Bilden einer dichtungsbildenden Struktur (3100), wobei das thermoformbare Material eine Übergangstemperatur im Bereich von 40°C bis 100°C hat.

14. Verfahren nach Anspruch 13, das ferner die folgenden Schritte umfasst:

Bereitstellen des Schaleneinsatzes (3250), eines Einsatzes für einen ersten Unterabschnitt (3162) einer dichtungsbildenden Struktur (3160), wobei der erste Unterabschnitt (3162) eine Nut (3130) beinhaltet, und des Abschnitts (3150) aus thermoformbarem Material;
Anordnen der bereitgestellten Strukturen in einem Werkzeug, so dass der Abschnitt (3150) aus thermoformbarem Material innerhalb der Nut (3130) angeordnet wird;
Überformen der Strukturen mit dem Formmaterial (3164), so dass das Formmaterial (3164) den Schaleneinsatz (3250), den ersten Unterabschnitt (3162) und den Abschnitt (3150) aus thermoformbarem Material verbindet.

15. Verfahren nach Anspruch 13, das ferner die folgenden Schritte umfasst:

Bereitstellen des Schaleneinsatzes (3250) und eines Einsatzes für einen Abschnitt (3160) einer dichtungsbildenden Struktur (3100), wobei der Einsatz für einen Abschnitt (3160) der dichtungsbildenden Struktur (3100) eine Nut (3130) beinhaltet;
Aneinanderformen der Einsätze mit dem Formmaterial;
Anordnen des Abschnitts (3150) aus thermoformbarem Material in der Nut (3130).

Revendications

1. Structure de formation d'étanchéité (3100) pour une interface patient (3000) permettant de traiter une respiration perturbée pendant le sommeil à l'aide d'une pression d'air par une distribution d'air aux voies respiratoires du patient,

dans laquelle la structure de formation d'étanchéité (3100) comprend une première section (3150) d'un matériau thermoformable et une seconde section (3160) d'un autre matériau ;
dans laquelle la première section (3150) est au moins partiellement confinée à l'intérieur de la seconde section (3160) ;
dans laquelle le matériau de la seconde section est un matériau alvéolaire et la seconde section (3160) comprend une membrane d'étanchéité destinée à assurer une étanchéité contre le visage du patient ; et
dans laquelle le matériau thermoformable a une température de transition s'inscrivant dans la plage de 40 °C à 100 °C.

2. Structure de formation d'étanchéité (3100) selon la revendication 1, dans laquelle la première section (3150) est complètement confinée à l'intérieur de la seconde section (3160).

3. Structure de formation d'étanchéité (3100) selon l'une quelconque des revendications précédentes, dans laquelle la seconde section (3160) comprend une section de bordure plane permettant une liaison avec une région de plateforme (3254).

4. Structure de formation d'étanchéité (3100) selon l'une quelconque des revendications précédentes, dans laquelle la seconde section (3160) comprend la membrane d'étanchéité (3110) et un rebord de support (3120).

5. Structure de formation d'étanchéité (3100) selon l'une quelconque des revendications précédentes, dans laquelle le matériau thermoformable est du polycaprolactane (PCL) et dans laquelle le matériau de la seconde section (3160) est un matériau élastique, tel que de la silicone, un élastomère thermoplastique et/ou un matériau alvéolaire.

6. Structure de formation d'étanchéité (3100) selon l'une quelconque des revendications précédentes, dans laquelle la seconde section (3160) comprend une rainure (3130) destinée à recevoir la première section (3150) du matériau thermoformable.

7. Structure de formation d'étanchéité (3100) selon la revendication 6, dans laquelle la rainure (3130) est positionnée de sorte que la rainure (3130) débouche vers l'extérieur de l'interface patient (3000) pendant l'utilisation de l'interface patient (3000).

8. Interface patient (3000) comprenant une structure de formation d'étanchéité (3100) selon l'une quelconque des revendications précédentes, dans laquelle l'interface patient (3000) comprend en outre une coque (3250).

9. Interface patient (3000) selon la revendication 8, dans laquelle l'interface patient (3000) comprend en outre une partie de support (3252) comprenant une région de plateforme (3254), dans laquelle la structure de formation d'étanchéité (3100) est fixée à la région de plateforme (3254), par exemple au moyen d'un adhésif (3190).

10. Interface patient (3000) selon la revendication 8 lorsqu'elle ne dépend pas de la revendication 2, dans laquelle la première section (3150), vue en coupe, est une section allongée, dans laquelle une extrémité longitudinale de la première section (3150) est reliée à la coque (3250) et les zones de la première section (3150) qui ne sont pas en contact avec la coque (3250) sont confinées par la seconde section (3260), dans laquelle l'extrémité longitudinale de la première section (3150) est reliée à la coque (3250) au moyen d'une interface (3256) permettant une liaison chimique, d'un verrouillage mécanique moulé (3258) ou d'un verrouillage mécanique sous la forme d'une liaison à encliquetage (3260).

11. Interface patient (3000) selon la revendication 8 lorsqu'elle ne dépend pas de la revendication 2, dans laquelle la première section (3150) comprend une section de périmètre (3152) et une pluralité de parties bandes (3154) reliant la section de périmètre (3152) à la coque (3250).

12. Interface patient (3000) selon la revendication 8, dans laquelle la seconde section (3160) comprend des sous-sections différentes (3162, 3164), dans laquelle une première sous-section (3162) comprend une rainure (3130) et dans laquelle la première section (3150) est positionnée dans la rainure (3130) au moyen d'une seconde sous-section (3164) qui relie également la structure de formation d'étanchéité (3100) à la coque (3250).

13. Procédé de fabrication d'une interface patient (3000) permettant de traiter une respiration perturbée pendant le sommeil à l'aide d'une pression d'air par une distribution d'air aux voies respiratoires d'un patient, le procédé comprenant les étapes consistant à :

relier une section (3150) d'un matériau thermoformable à un insert de coque (3250) à l'aide, de préférence, du moyen selon la revendication 8 ;
surmouler au moins la section (3150) de matériau thermoformable avec un matériau de moulage (3164) et former ainsi une structure de formation d'étanchéité (3100), le matériau thermoformable ayant une température de transition s'inscrivant dans la plage de 40 °C à 100 °C.

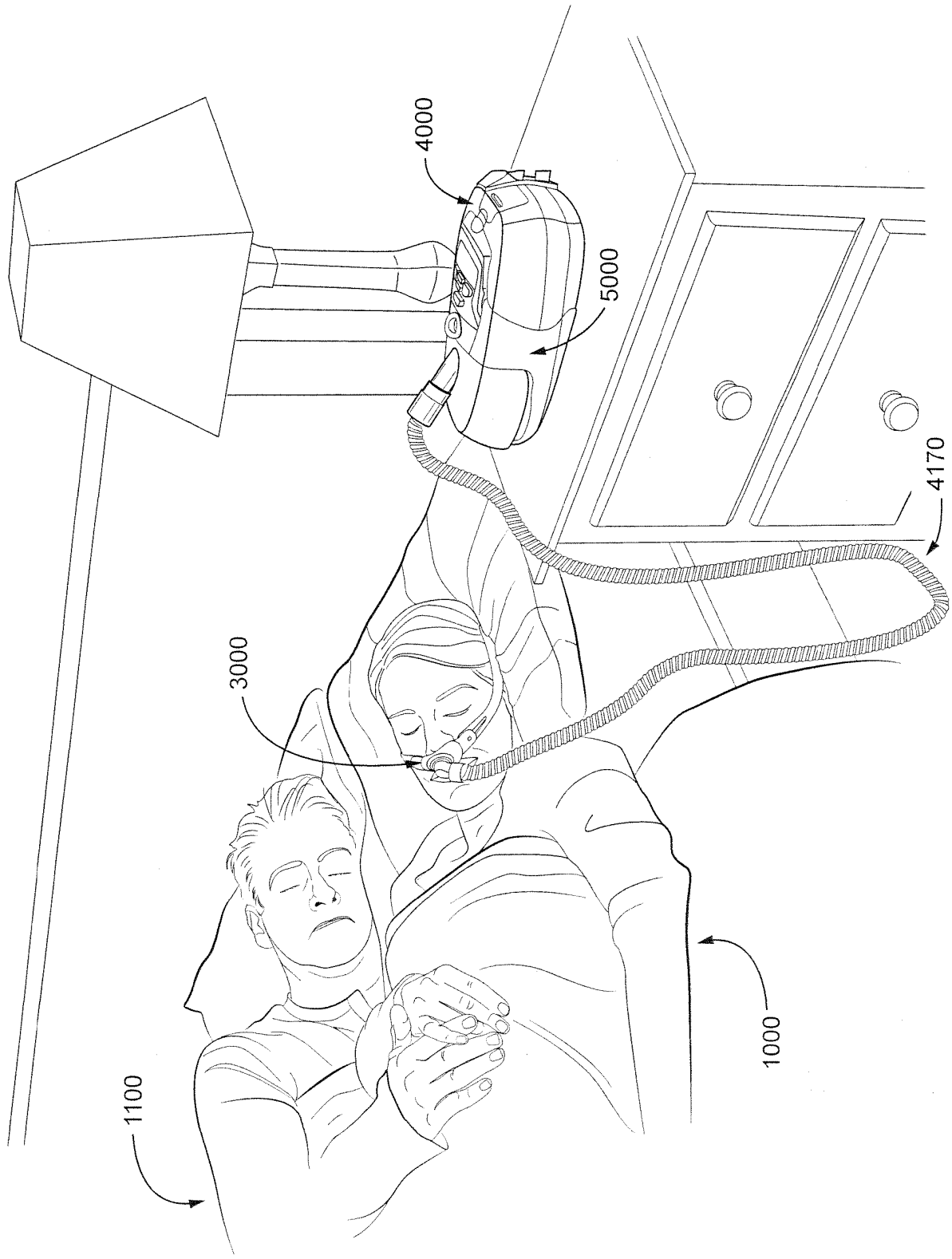
14. Procédé selon la revendication 13, comprenant en outre les étapes consistant à :

utiliser l'insert de coque (3250), un insert destiné à une première sous-section (3162) d'une structure de formation d'étanchéité (3160), dans lequel la première sous-section (3162) comprend une rainure (3130), et la section (3150) de matériau thermoformable ;
positionner les structures utilisées dans un outil de sorte que la section (3150) de matériau thermoformable soit positionnée à l'intérieur de la rainure (3130) ;
surmouler les structures avec le matériau de moulage (3164), de sorte que le matériau de moulage (3164) relie l'insert de coque (3250), la première sous-section (3162) et la section (3150) de matériau thermoformable.

15. Procédé selon la revendication 13, comprenant en outre les étapes consistant à :

utiliser l'insert de coque (3250) et un insert destiné à une section (3160) d'une structure de formation d'étanchéité (3100), dans lequel l'insert destiné à une section (3160) de la structure de formation d'étanchéité (3100) comprend une rainure (3130) ;
mouler solidairement les inserts avec le matériau de moulage ;
positionner la section (3150) de matériau thermoformable dans la rainure (3130).

Fig. 1a



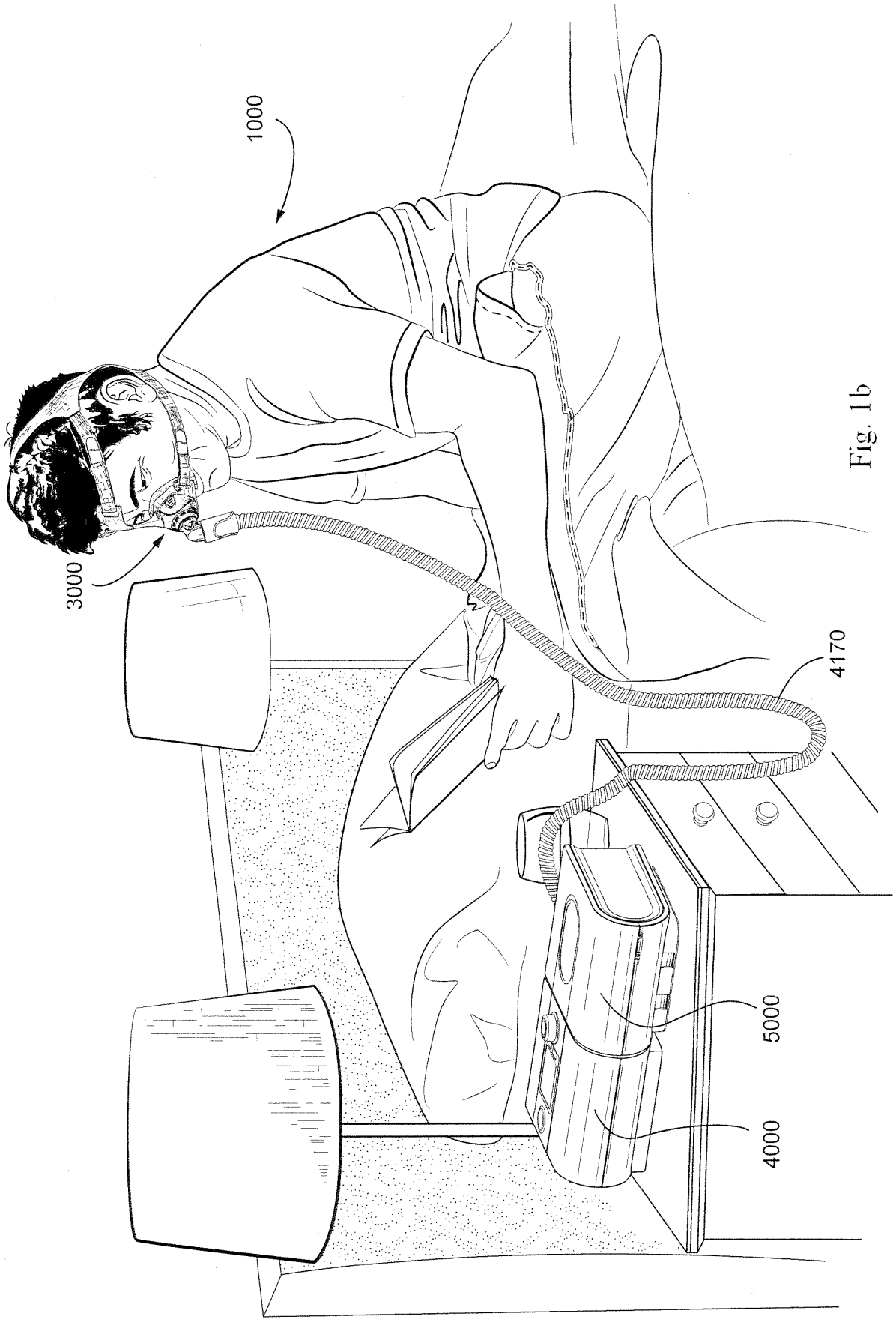


Fig. 1b

Fig. 1c

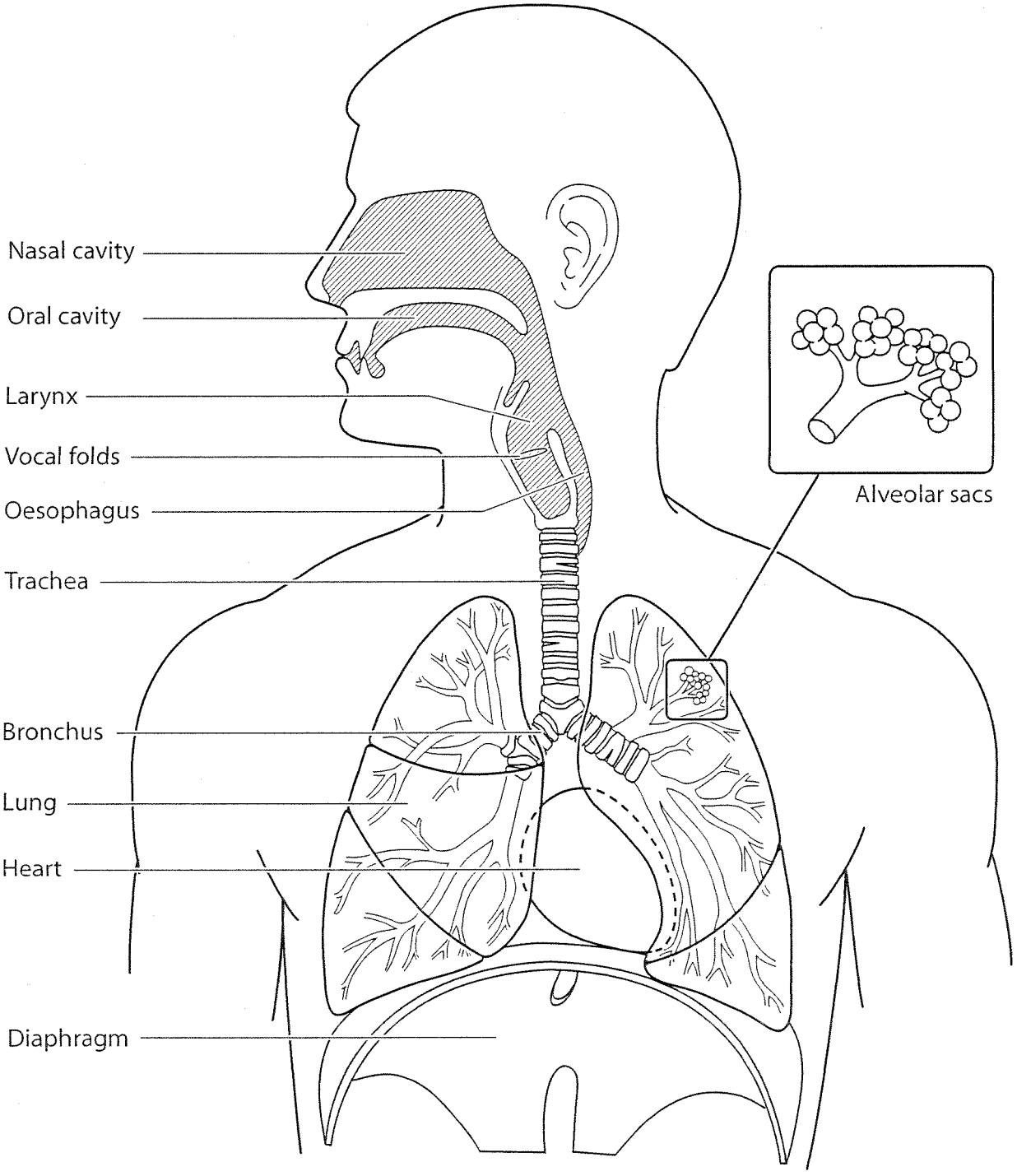

Nasal cavity
Oral cavity
Larynx
Vocal folds
Oesophagus
Trachea
Bronchus
Lung
Heart
Diaphragm
Alveolar sacs

Fig. 2a

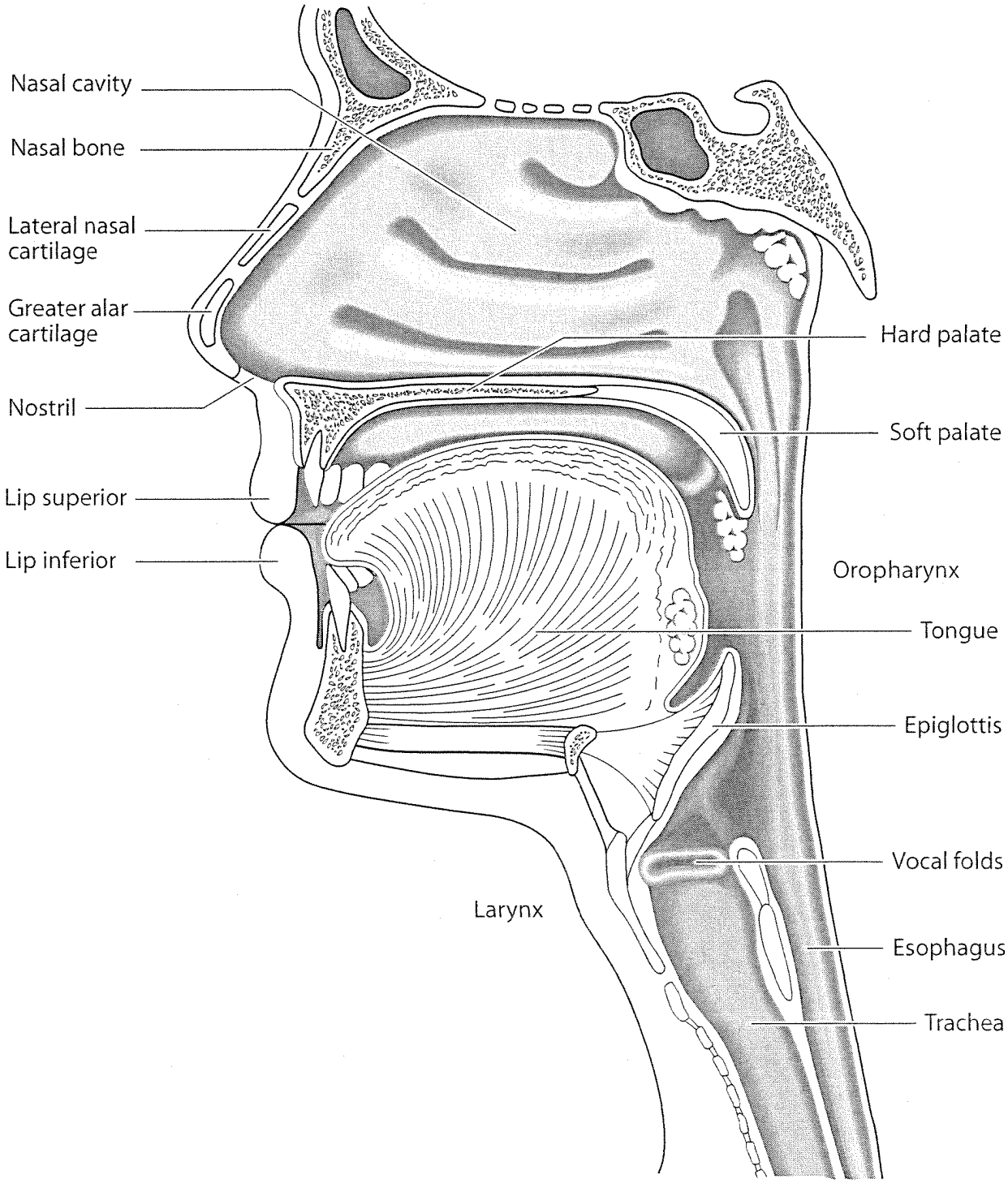

Nasal cavity
Nasal bone
Lateral nasal cartilage
Greater alar cartilage
Nostril
Lip superior
Lip inferior
Hard palate
Soft palate
Oropharynx
Tongue
Epiglottis
Vocal folds
Larynx
Esophagus
Trachea

Fig. 2b

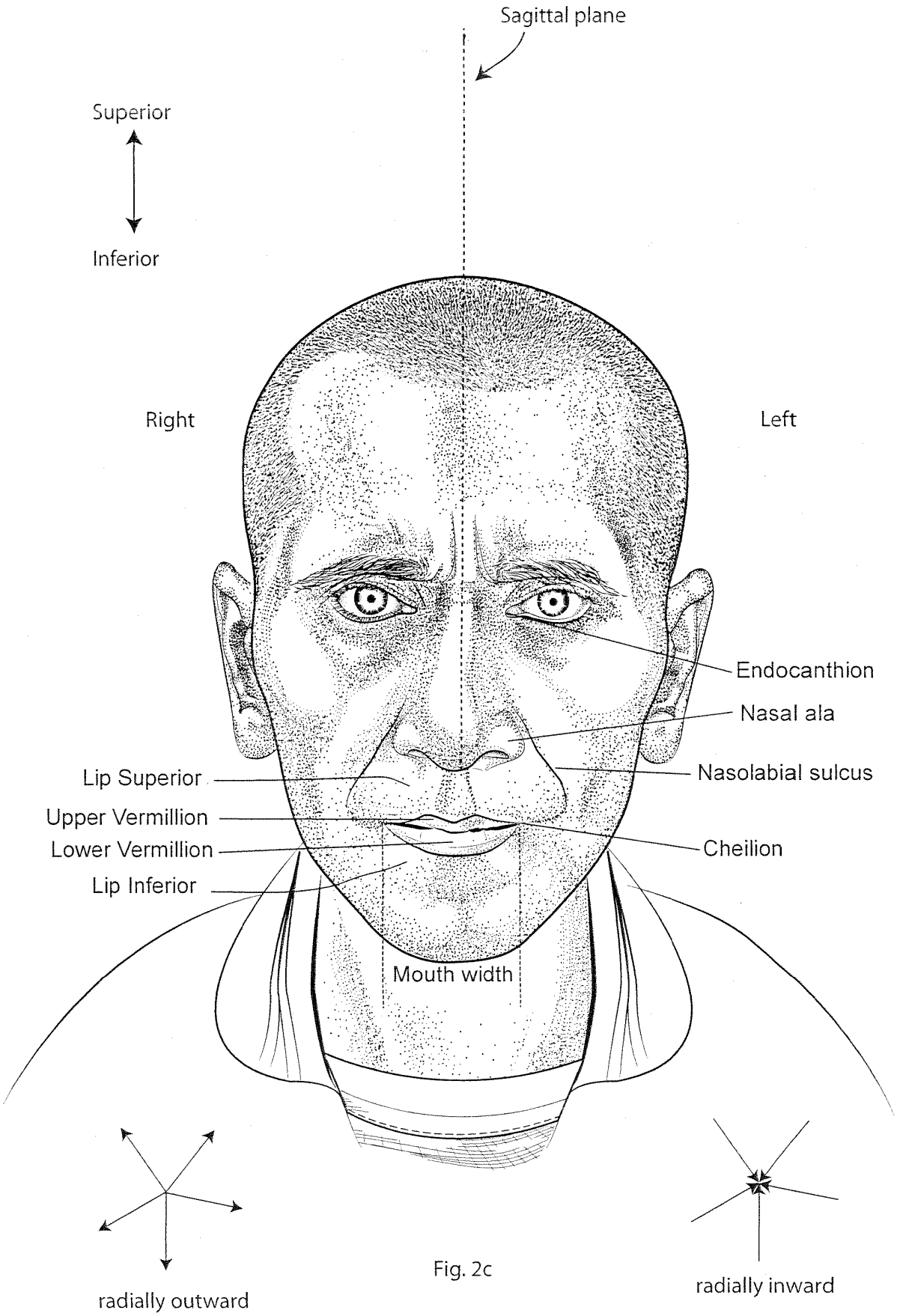

Sagittal plane
Superior
Inferior
Right
Left
Endocanthion
Nasal ala
Nasolabial sulcus
Lip Superior
Upper Vermillion
Lower Vermillion
Lip Inferior
Cheilion
Mouth width
radially outward
radially inward

Fig. 2c

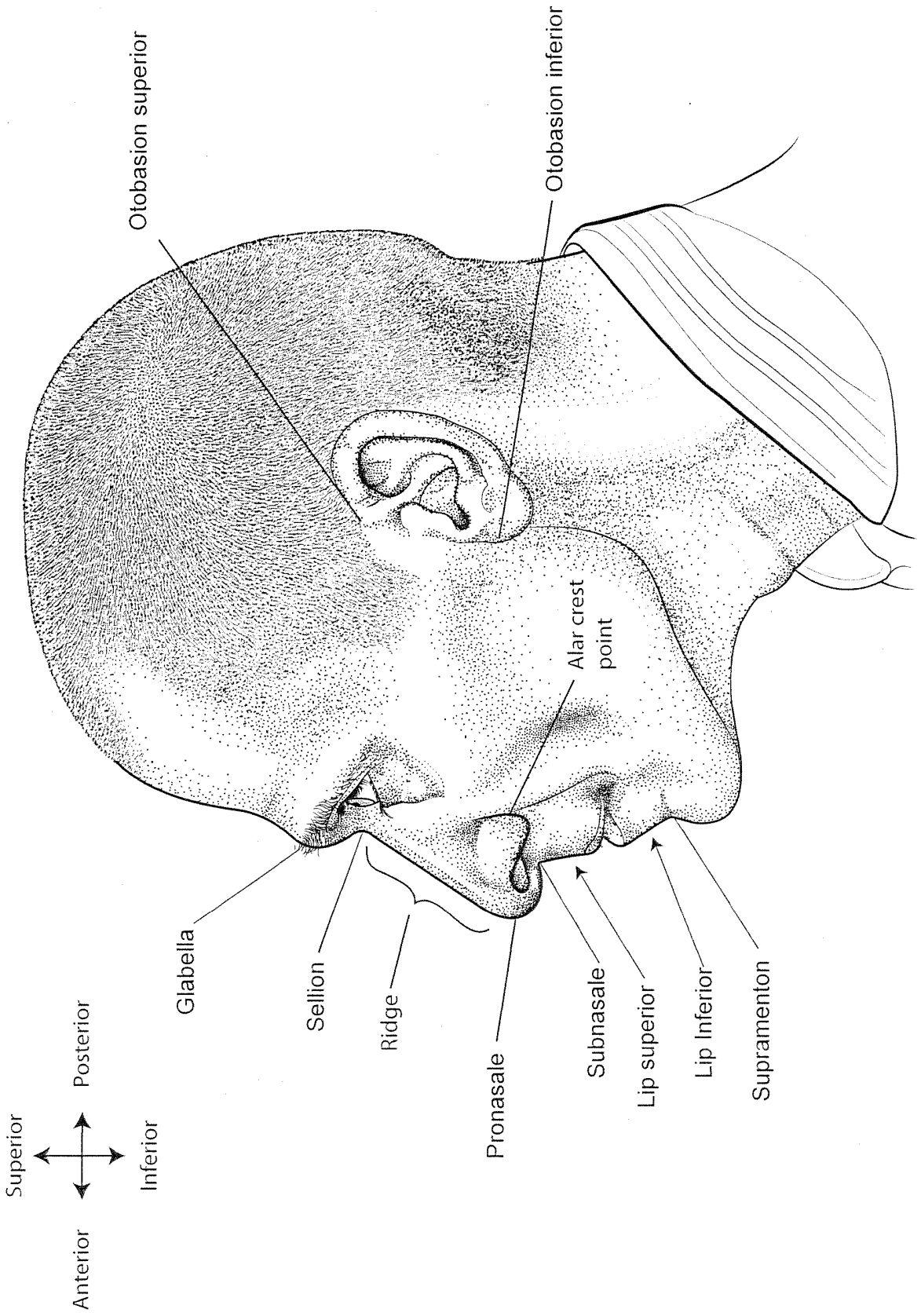

Otobasion superior
Otobasion inferior
Alar crest point
Glabella
Sellion
Ridge
Pronasale
Subnasale
Lip superior
Lip Inferior
Supramenton
Superior
Posterior
Anterior
Inferior

Fig. 2d

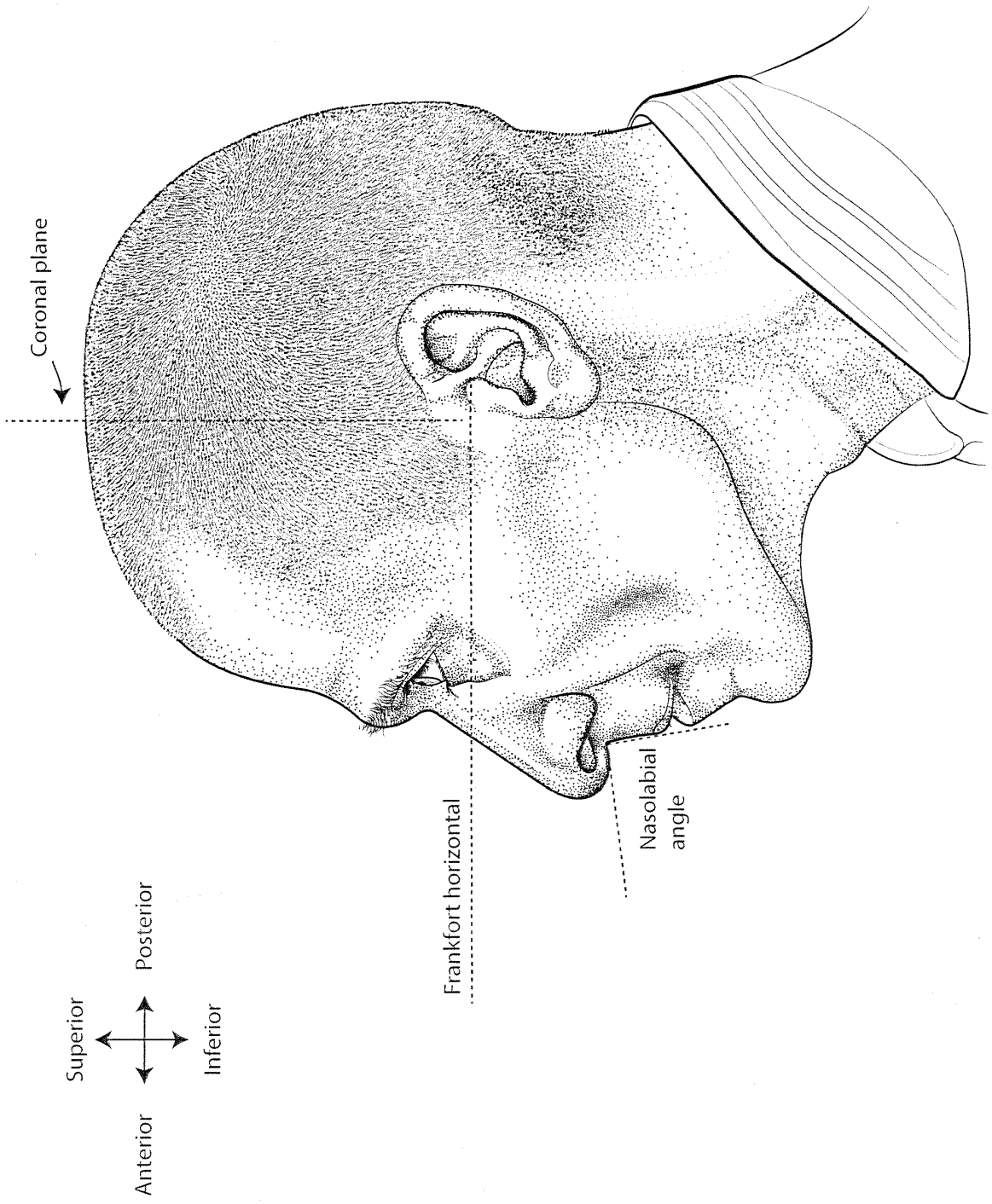

Coronal plane
Frankfort horizontal
Nasolabial angle
Superior
Posterior
Inferior
Anterior

Fig. 2e

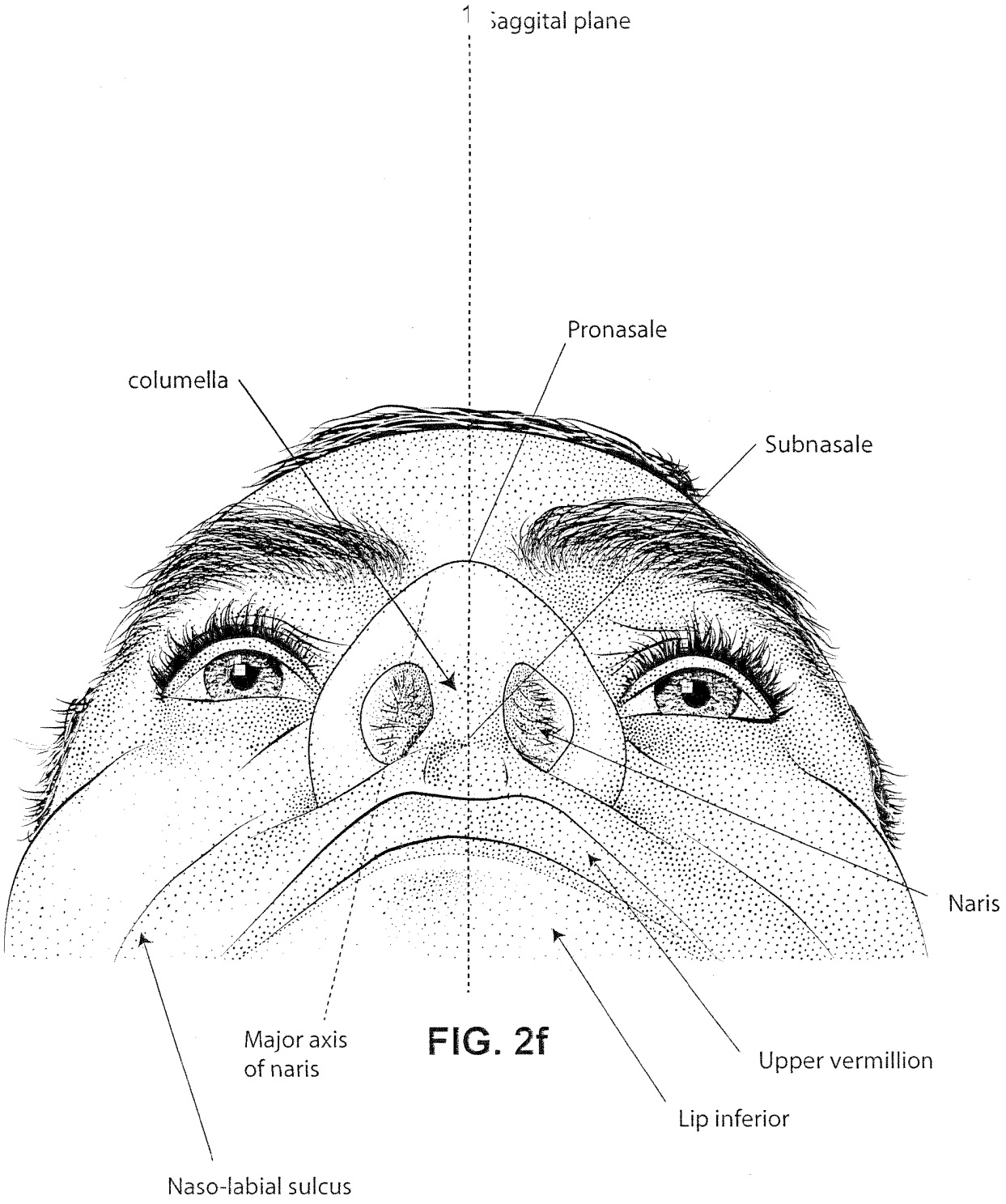

Saggital plane
Pronasale
columella
Subnasale
Naris
Major axis
of naris
Upper vermillion
Lip inferior
Naso-labial sulcus

FIG. 2f

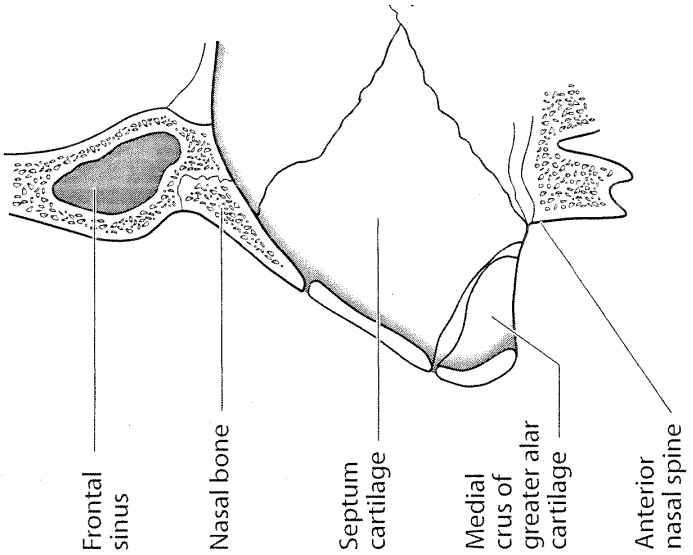


Fig. 2i

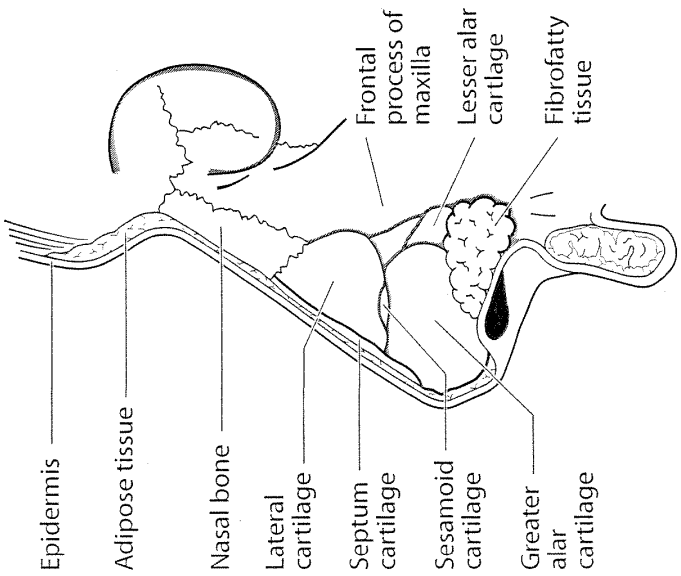


Fig. 2h

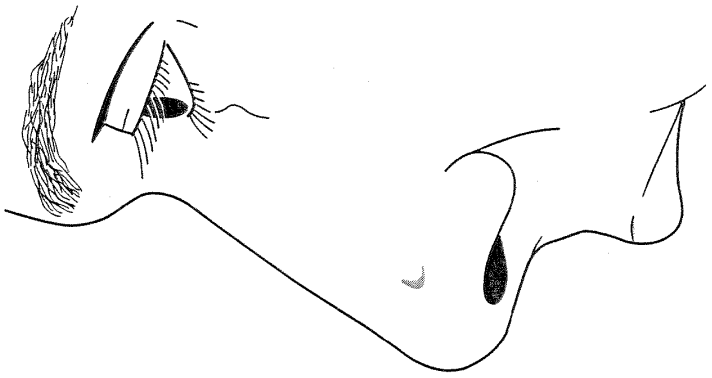


Fig. 2g

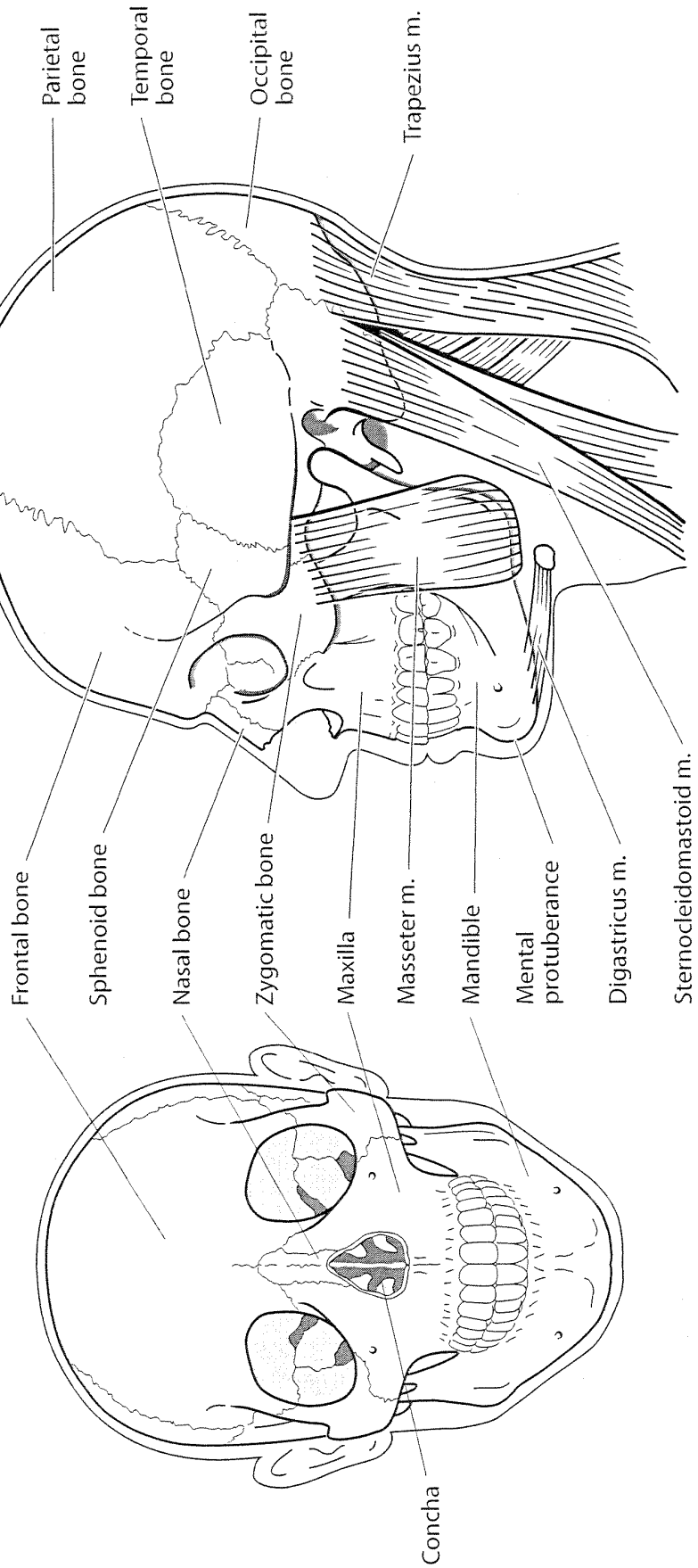

Parietal bone
Temporal bone
Occipital bone
Trapezius m.
Frontal bone
Sphenoid bone
Nasal bone
Zygomatic bone
Maxilla
Masseter m.
Mandible
Mental protuberance
Digastricus m.
Sternocleidomastoid m.
Concha

Fig. 2j

Fig. 2k

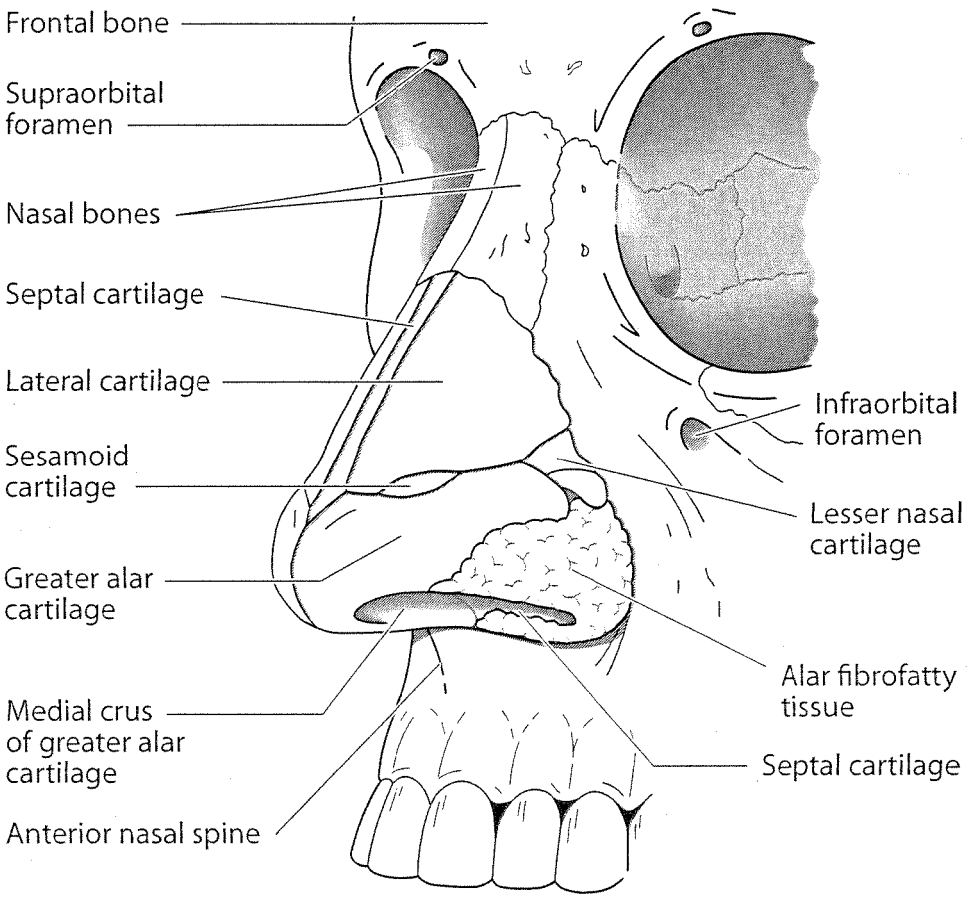

Frontal bone
Supraorbital foramen
Nasal bones
Septal cartilage
Lateral cartilage
Sesamoid cartilage
Greater alar cartilage
Medial crus of greater alar cartilage
Anterior nasal spine
Infraorbital foramen
Lesser nasal cartilage
Alar fibrofatty tissue
Septal cartilage

Fig. 2I

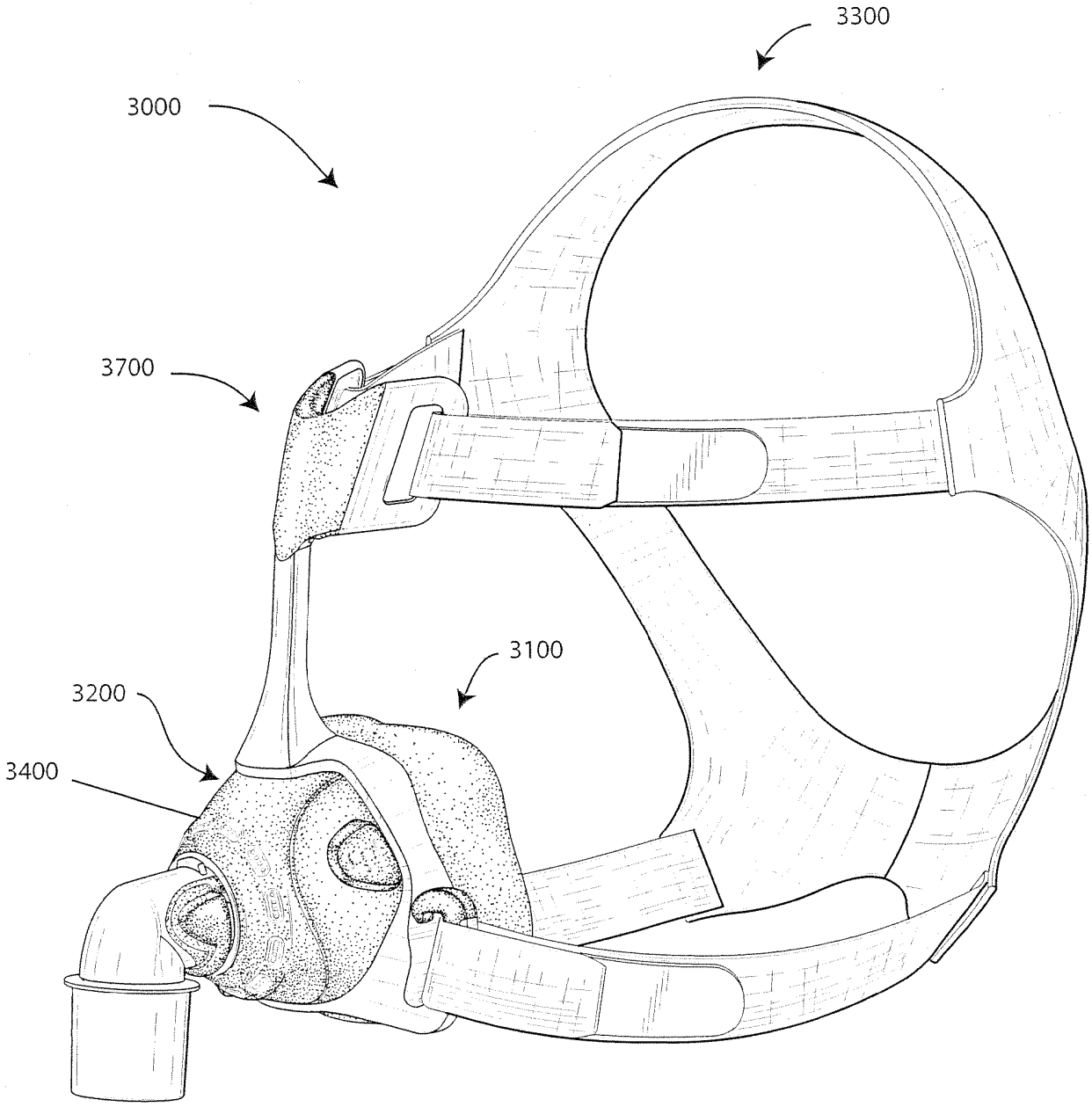


Fig. 3a

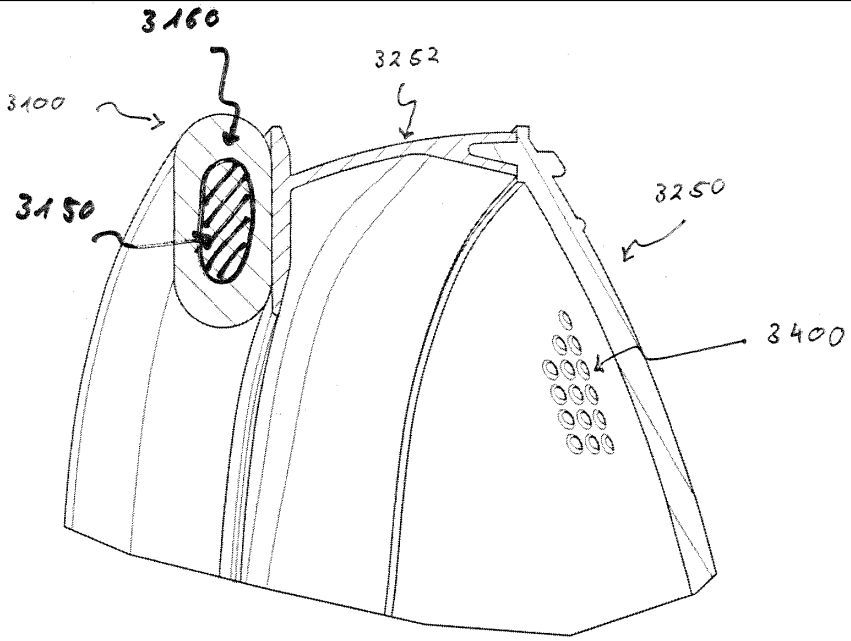

3160
3252
3100
3150
3250
3400

Fig. 4b

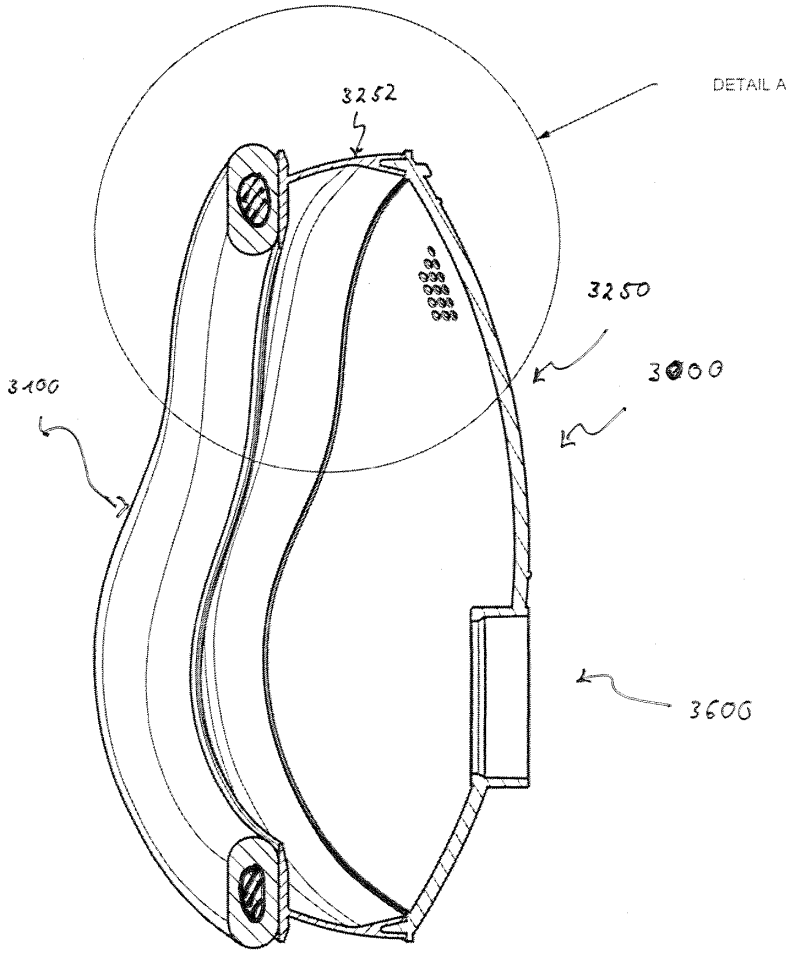

DETAIL A
3252
3250
3000
3100
3600

Fig. 4a

Fig. 5a

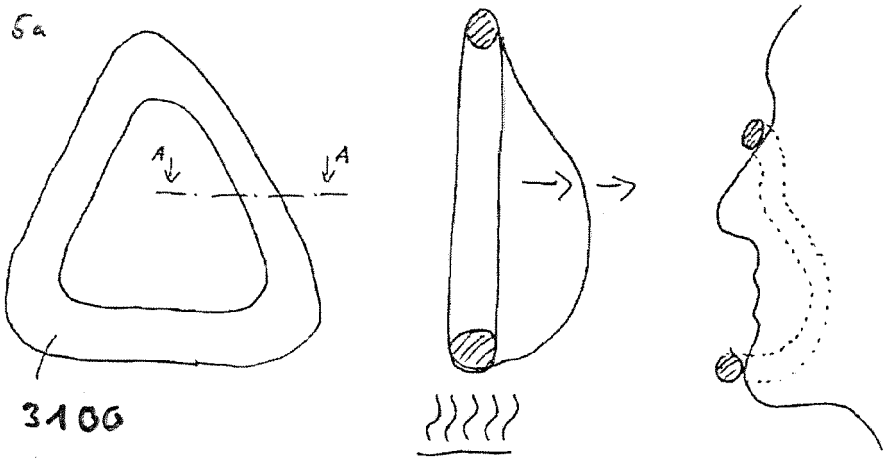


Fig. 5b

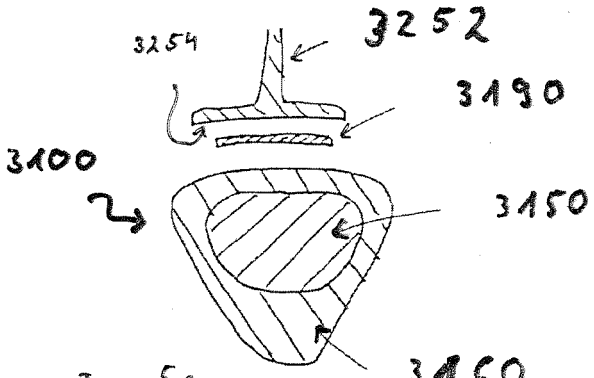
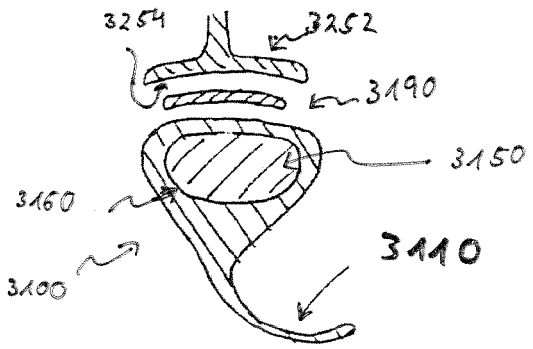


Fig. 5c



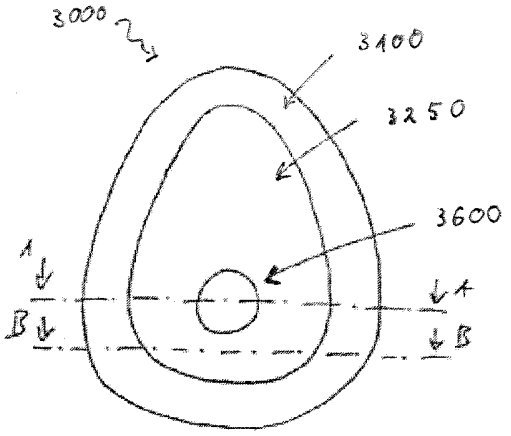


Fig. 6a

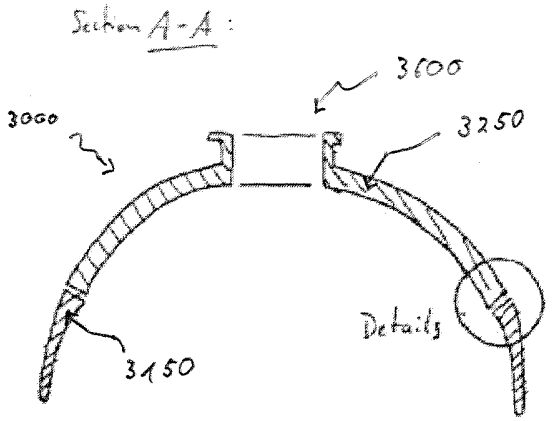


Fig. 6b

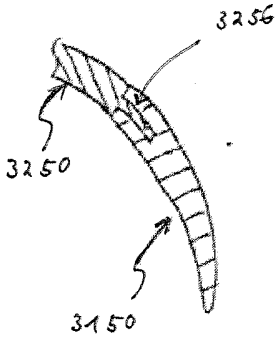


Fig. 6c

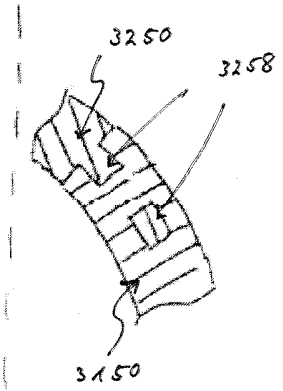


Fig. 6d

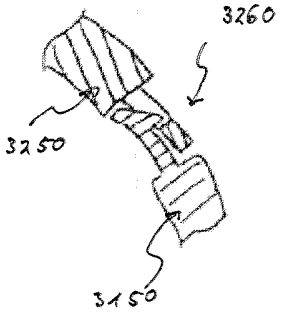


Fig. 6e

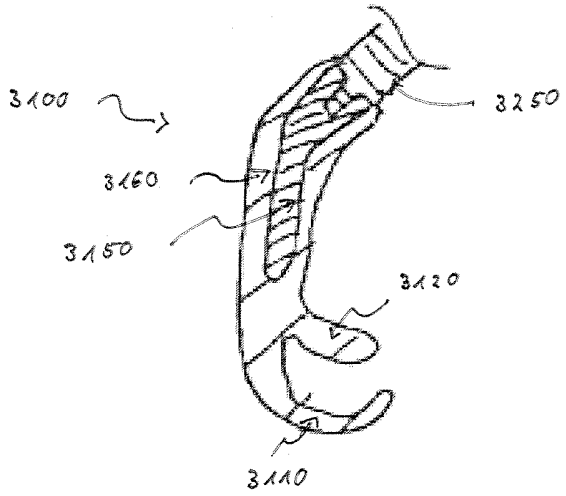


Fig. 6f

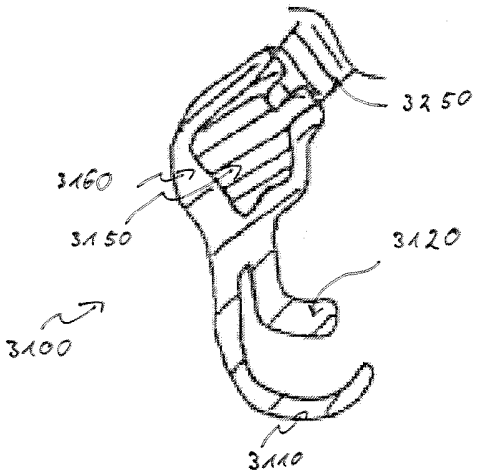


Fig. 6g

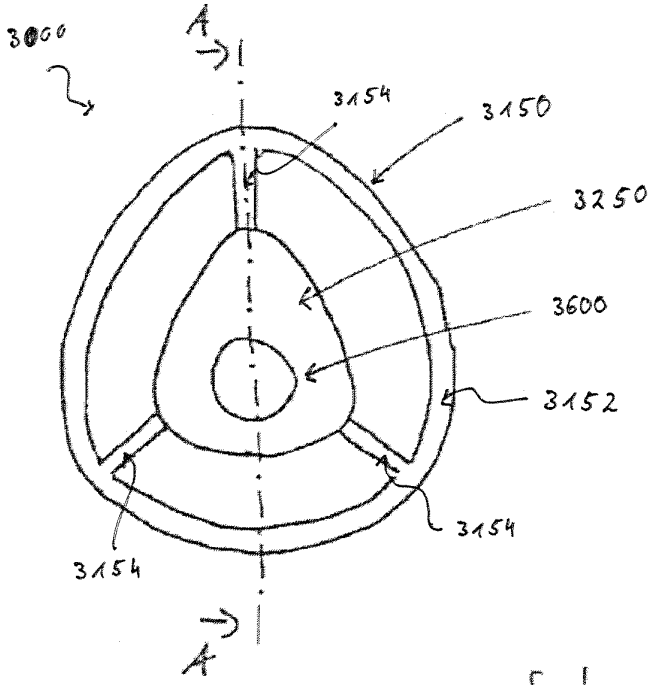


Fig. 7a

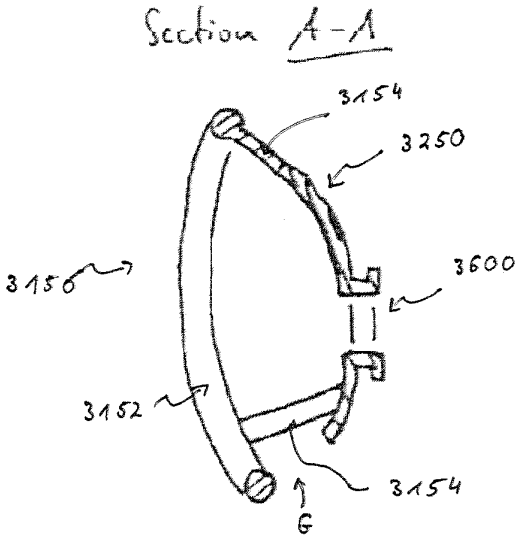


Fig. 7b

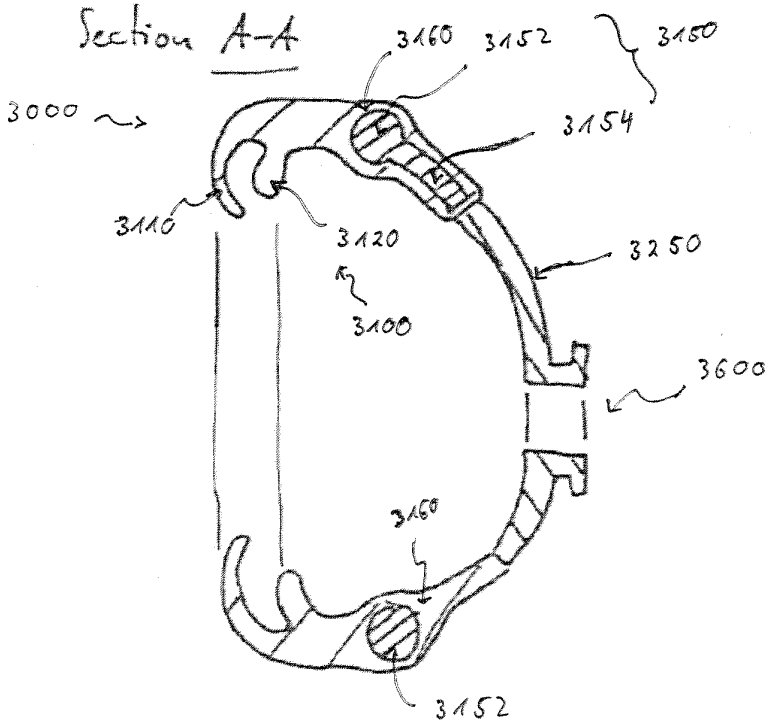


Fig. 7c

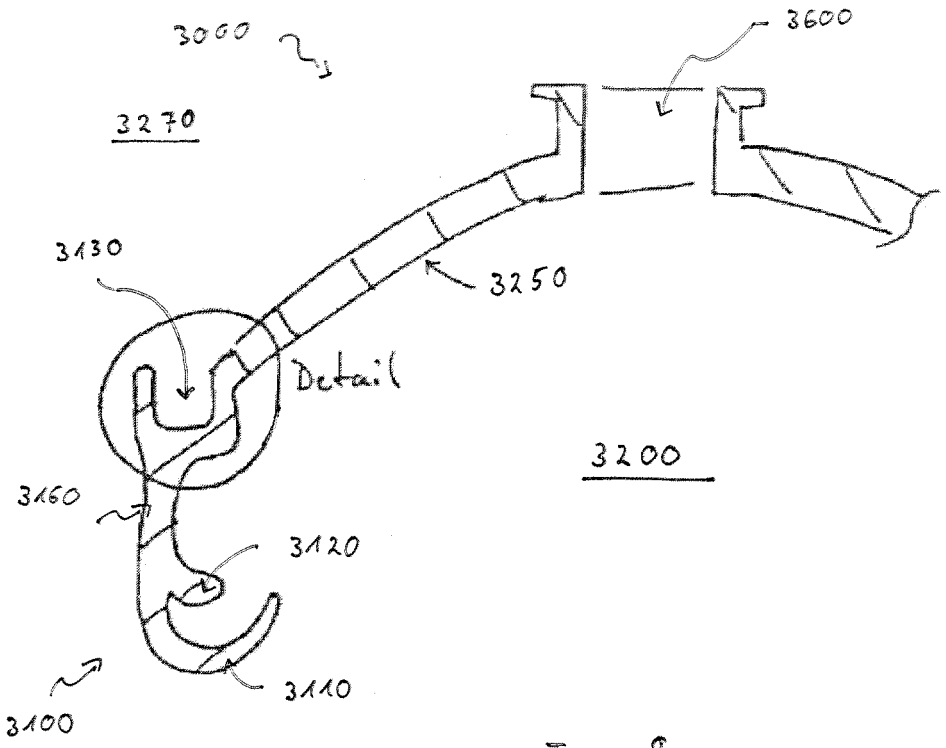

3000
3600
3270
3130
3250
Detail
3200
3160
3120
3110
3100

Fig. 8a

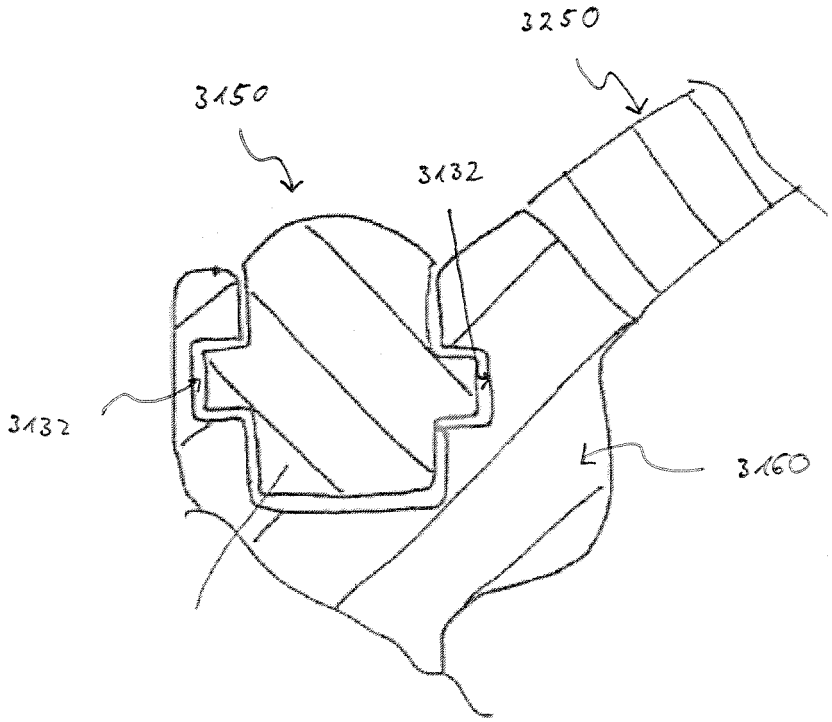

3250
3150
3132
3132
3160

Fig. 8b

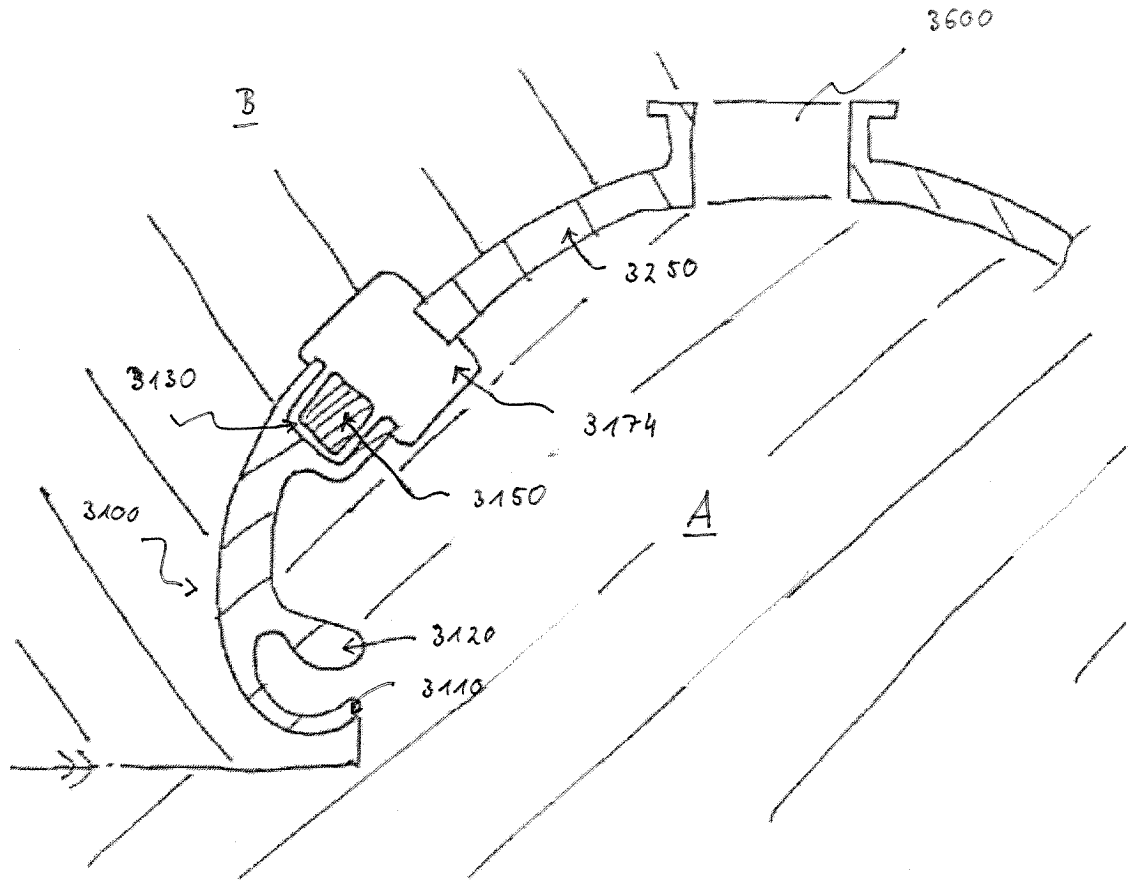

3600
B
3250
3130
3174
3150
3100
A
3120
3110

Fig. 9a

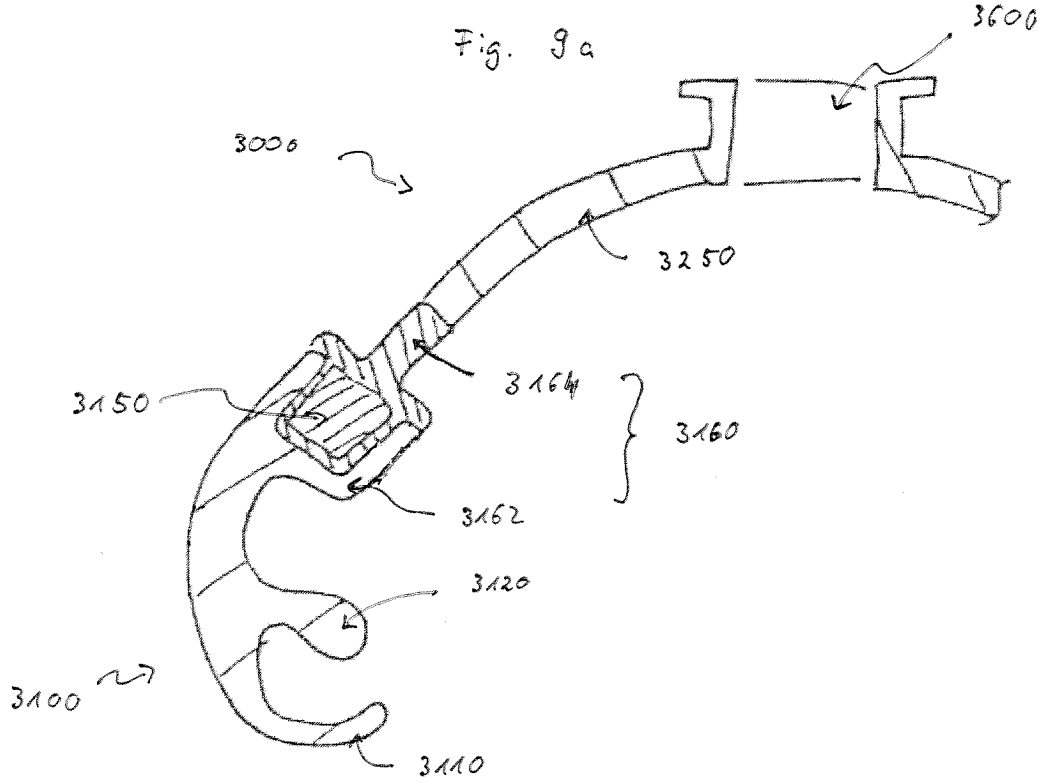

3600
3000
3250
3150
3164
3160
3162
3120
3100
3110

Fig. 9b

REFERENCES CITED IN THE DESCRIPTION

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